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I. INTRODUCTION

A. Purpose and Summary, and
B. Background and Need for Legislation

Nearly four decades ago, Congress enacted the Medicare program to help provide health care to our nation's seniors. Medicare has improved and lengthened the lives of millions of people. In recent years, Congress has both successfully slowed Medicare's growth rate and added new preventive benefits to keep seniors healthier. Yet Medicare has still not met its true promise because it remains mired in a rigid administrative structure that can only change when Congress enacts a law.

When Medicare was enacted, there were few prescription drugs, and most care was delivered in hospitals and physician offices. Consequently, Medicare did not cover prescription drugs. While about two-thirds of seniors have some prescription drug coverage through various sources, access to such coverage has been declining and oftentimes remains inadequate. Many other seniors lack prescription drug coverage, and therefore, they lack the bargaining power to reduce their drug costs.

Prescription drugs are an integral part of health care today. They prevent and manage diseases and most often are less invasive and costly than alternative health care options (e.g. surgery, hospitalization, nursing home admission, etc.). Most private health plans have voluntarily integrated prescription drugs into their benefits. Nobody today with a blank sheet of paper would design a health care program for seniors that excluded prescription drugs. Yet, the absence of a prescription drug benefit epitomizes how Medicare has not kept pace with modern medicine. While a Medicare prescription drug benefit is long overdue, it is not the only problem afflicting a program so many cherish and want to strengthen.

Irrational and unpredictable payments to physicians are just one example of what is wrong with Medicare's reimbursement policy. While health costs are escalating under the current Sustainable Growth Rate formula, payments to physicians under current law would be substantially reduced. Patients' access to physicians will suffer and the doctors beneficiaries rely on will only become more demoralized. Similarly, rural hospitals continue to struggle and are not paid equitably compared to large urban hospitals. In addition, numerous Medicare+Choice plans are withdrawing from the program and are substantially cutting benefits because government payments are not related to the actual cost of providing health care.

At the same time, Medicare is overpaying on other counts, such as for durable medical equipment. The Office of Inspector General has documented that taxpayers and Medicare beneficiaries are paying millions more for durable medical equipment than other programs, such as the Federal Employees Health Benefit Program (FEHBP). Similarly, numerous studies by the General Accounting Office, Office of Inspector General and others have documented tremendous overpayments to oncologists and other physicians for currently covered prescription drugs. In some cases, the beneficiary copay exceeds the actual acquisition cost of the drug.

In addition, the health care professionals serving Medicare beneficiaries are being crushed by more than 130,000 pages of overly burdensome regulations -- four times more than those governing the Internal Revenue Code. This over-regulation hampers efforts to provide quality care to seniors, and it must be changed.

Finally, and most importantly, Medicare's long-term viability is not on stable ground. When Medicare was enacted, there were more than six workers per beneficiary. Today, there are about four workers per beneficiary. After the baby-boom generation retires (which starts at the end of this decade), there will be about two workers per beneficiary. Absent any change in law, Medicare costs will nearly double over the next 10 years. Medicare needs to become more efficient.

This bill addresses all of these issues and more.

First and foremost, the bill provides a voluntary, affordable prescription drug benefit as an entitlement to all beneficiaries. The proposal is within the $400 billion over 10 years allocated under the budget resolution. Under the bill, Medicare beneficiaries would pay a $250 deductible and then receive 80 percent coverage of their annual drug costs up to $2,000. This 80-20 benefit looks like standard coverage offered by employer plans, and today nearly two-thirds of beneficiaries spend less than $2,000 on drugs annually. In addition, the bill provides catastrophic protection after an individual has incurred $3,500 in out-of-pocket costs. At that threshold, 100 percent of costs will be covered. The Congressional Budget Office (CBO) estimates the average monthly beneficiary premium to be about $35.

Additionally, the bill targets resources to those who need them most. For low-income seniors up to 135 percent of poverty, premiums would be fully subsidized and all cost-sharing, except for nominal copays, would be covered. Those with incomes between 135 and 150 percent would also receive assistance for their premiums. Seniors with incomes above $60,000 or couples with incomes above $120,000 would have a higher catastrophic threshold, but would receive the same front-end benefit. This higher threshold would affect only about five percent of individuals.

The prescription drug benefit would be delivered through competing integrated health plans and private sector entities that already deliver pharmaceutical benefits for millions of people, including every Member of Congress. The bill permits and encourages these plans to utilize private sector tools to aggressively negotiate lower drug prices and provide better service for beneficiaries. By exempting prices negotiated for Medicare beneficiaries from the Medicaid "best price" provision, the bill encourages steep discounting by pharmaceutical manufacturers that would save taxpayers and beneficiaries billions of dollars. The private sector delivery of benefits is backed up by a government guarantee that all seniors in every area of the country must be covered. Indeed, the Congressional Budget Office and the Centers for Medicare and Medicaid Services (CMS) Office of the Actuary predicts that more than 95 percent of the seniors that lack coverage would voluntarily sign up for this benefit.

The bill would provide seniors with more and better choices for the delivery of their health care. The Medicare+Choice program would be fundamentally reformed by re-linking payments to fee-for-service costs and permitting plans to bid their actual costs, beginning in

2006. Plans would be paid what they bid and savings would be split 75 percent-25 percent between the beneficiary and government for plans that bid below the benchmark. The bill would also implement the President's "enhanced fee-for-service" program, which provides for regional, open-network plans offering better integrated care.

In 2010, the bill would put Medicare on a more stable funding path by moving to a FEHBP-style of competition between plans. Nothing would change Medicare's entitlement to a defined set of benefits, but costs between fee-for-service and private plans would be directly compared. Beneficiaries would be rewarded for enrolling in more efficient plans, regardless of whether the plans are private or traditional fee-for-service. This program would only apply in areas with significant private plan penetration (at least equal to the national average market share), and the fee-for-service plan would have disproportionate influence in establishing the benchmark. This transition would be phased in over five years. This provision provides Medicare the best chance to bend its growth rate in the out-years by enabling beneficiaries to make efficient and rational choices, and by permitting the government to share in the savings when beneficiaries select cost-effective plans.

More than 179 different patient groups, provider groups, and employers have endorsed this legislation because it provides a meaningful benefit, modernizes irrational reimbursements, and reduces burdensome regulatory structures that undermine the quality and accessibility of care. The bill reforms physician payments, addresses payment inequities for rural hospitals and home health providers, and makes responsible decisions on provider reimbursements based on the Medicare Payment Advisory Commission's recommendations. More importantly, the legislation sets Medicare on a path of more rational pricing—determined by the marketplace, rather than government edict—through moving durable medical equipment, currently covered drugs, and Medicare's contractors into a competitive system. In addition to creating a more rational system that saves money over time, these changes get Congress out of the business of micro-managing payments to providers across communities in America based on political decisions in Washington.

The bill provides clear improvements for preventive benefits for beneficiaries. For the first time, in order to diagnose problems early and keep seniors healthy, Medicare would cover initial physicals and provide coverage for cholesterol screening. The bill would also provide better-coordinated care for the numerous Medicare beneficiaries who suffer from multiple chronic illnesses.

The bill also includes regulatory and contracting reforms—reforms that passed the House twice in the 107th Congress—to reduce unnecessary regulation and modernize how Medicare selects its contractors.

Finally, the bill also establishes a new Medicare Benefits Administration (MBA) to manage and oversee the Medicare Advantage and Enhanced Fee-for-Service Programs as well as the prescription drug benefit. Creating of the MBA eliminates the inherent conflict-of-interest in requiring a government-run fee-for-service plan to regulate competing private plans.

C. Legislative History

Legislative Hearings

During the 107th and 108th Congresses, the Committee on Ways and Means, and its Subcommittee on Health, held 24 hearings exploring how Medicare should be strengthened and modernized. These hearings, which examined all aspects of the Medicare program, included expert testimony from academic, beneficiary and provider representatives. The following lists the hearings in the 107th and 108th Congresses in reverse chronological order:

108th Congress:

May 1, 2003: Medicare Cost-Sharing and Medigap Reform (Subcommittee on Health)

Witnesses:

Glenn M. Hackbarth, Chairman, Medicare Payment Advisory Commission

Stephen W. Still, Esq., Maynard, Cooper & Gale, P.C., Birmingham, Alabama, on behalf of Torchmark Corporation, Birmingham, Alabama, and United American Insurance Company, McKinney, Texas

Richard White, Vice President, Individual Project Management, Southeast Region, Anthem Blue Cross and Blue Shield, Roanoke, Virginia

Patricia Neuman, Sc. D., Vice President and Director, Medicare Policy Project, Kaiser Medicare Policy Project, Henry J. Kaiser Family Foundation

April 9, 2003: Hearing on Expanding Coverage of Prescription Drugs in Medicare (Full Committee)

Witnesses:

Douglas Holtz-Eakin, Ph.D., Director, Congressional Budget Office

The Honorable David M. Walker, Comptroller General, U.S. General Accounting Office

Bruce Stewart, Ph.D., Director, Peter Lamy Center on Drug Therapy and Aging, University of Maryland, Baltimore, Maryland

Mark V. Pauly, Ph.D., Chairperson, Health Care Systems Department, The Wharton School, University of Pennsylvania, Philadelphia, Pennsylvania

Uwe Reinhardt, Ph.D., Professor, Economics and Public Affairs, Department of Economics, and Woodrow Wilson School of Public and International Affairs, Princeton University, Princeton, New Jersey

March 6, 2003: Hearing on the MedPAC Report on Medicare Payment Policies (Subcommittee on Health)

Witnesses:

Glenn M. Hackbarth, Chairman, MedPAC

James Jaruzewicz, President and Chief Executive Officer, Visiting Nurses Association of Erie County, Erie, Pennsylvania, on behalf of the Visiting Nurses Association of America

Larry C. Buckelew, President and Chief Executive Officer, Gambro Healthcare U.S., and Chairman, Renal Leadership Council

William G. Plested, III, M.D., Chair-Elect, American Medical Association

Mary K. Ousley, Chairman, American Health Care Association

Dennis Barry, President and Chief Executive Officer, Moses Cone Health System, Greensboro, North Carolina, and Chairman, Board of Trustees, American Hospital Association

Betty Severyn, Member, Board of Directors, AARP

February 25, 2003: Hearing on Eliminating Barriers to Chronic Care Management in Medicare (Subcommittee on Health)

Witnesses:

Stuart Guterman, Director, Office of Research, Development and Information, Centers for Medicare and Medicaid Services

Jeff Lemieux, Senior Economist, Progressive Policy Institute

Ed Wagner, M.D., Director, MacColl Institute for Healthcare Innovation, Center for Health Studies, Group Health Cooperative, Seattle, Washington

George A. Taler, M.D., Director, Long Term Care, Department of Medicine, Washington Hospital Center, on behalf of the American Geriatric Society

Jan Berger, M.D., Senior Vice President, Clinical Quality and Support, Caremark Rx Incorporated, Northbrook, Illinois

February 13, 2003: Hearing on Medicare Regulatory and Contracting Reform (Subcommittee on Health)

Witnesses:

The Honorable Thomas A. Scully, Administrator, Centers for Medicare and Medicaid Services

Douglas L. Wood, M.D., Vice Chair, Department of Medicine, Mayo Clinic and Foundation, Rochester, Minnesota

Michael Luebke, President, Verizon Information Technologies Inc., Tampa, Florida

Tony Fay, Vice President, Government Affairs, Province Healthcare Company, Brentwood, Tennessee, on behalf of the American Hospital Association

J. Edward Hill, M.D., Chairman, Board of Trustees, American Medical Association

Janet B. Wolf, President, Munson Home Health, Traverse City, Michigan, and Past President, Board of Directors, Michigan Home Health Association, Okemos, Michigan, on behalf of the National Association for Home Care and Hospice

Judith A. Ryan, Ph.D., President and Chief Executive Officer, Evangelical Lutheran Good Samaritan Society, Sioux Falls, South Dakota, on behalf of the American Health Care Association

Michael Carius, M.D., Immediate Past President, American College of Emergency Physicians, Norwalk, Connecticut, and Founding Member, Alliance of Specialty Medicine

Vicki Gottlich, Attorney, Healthcare Rights Project, Center for Medicare Advocacy, Inc.

February 6, 2003: Hearing on the President's Fiscal Year 2004 Budget with U.S. Department of Health and Human Services (Full Committee)

Witness:

The Honorable Tommy G. Thompson, Secretary, U.S. Department of Health and Human Services

107th Congress:

October 3, 2003 Medicare Payments for Currently Covered Prescription Drugs (Subcommittee on Health)

July 23, 2002 Medicare's Geographic Cost Adjusters (Subcommittee on Health)

April 17, 2002	Integrating Prescription Drugs into Medicare (Full Committee)
April 16, 2002	Promoting Disease Management in Medicare (Subcommittee on Health)
March 14, 2002	Medicare Supplemental Insurance (Subcommittee on Health)
March 7, 2002	Health Quality and Medical Errors (Subcommittee on Health)
February 28, 2002	Reforming Physician Payments (Subcommittee on Health)
December 4, 2001	Status of the Medicare+Choice Program (Subcommittee on Health)
September 25, 2001	H.R. 2768, Medicare Regulatory and Contracting Reform Act (Subcommittee on Health)
July 19, 2001	Administration's Principles to Strengthen and Modernize Medicare (Full Committee)
June 12, 2001	Rural Health Care in Medicare (Subcommittee on Health)
May 9, 2001	Strengthening Medicare: Modernizing Beneficiary Cost-Sharing (Subcommittee on Health)
May 1, 2001	Medicare+Choice: Lessons for Reform (Subcommittee on Health)
March 27, 2001	Laying the Groundwork for a Prescription Drug Benefit (Subcommittee on Health)
March 20, 2001	Medicare Solvency (Full Committee)
March 15, 2001	Bringing Regulatory Relief to Beneficiaries and Providers (Subcommittee on Health)
March 14, 2001	Administration's Health and Welfare Priorities (Full Committee)
February 28, 2001	Perspectives on Medicare Reform (Subcommittee on Health)

On April 11, 2003, Congress agreed to the conference report for H. Con. Res. 95, "Establishing the congressional budget for the United States Government for fiscal year 2004 and setting forth appropriate budgetary levels for fiscal years 2003 and 2005 through 2013," which provided $400 billion over 10 years for Medicare modernization and prescription drugs.

On June 16, 2003, Committee on Ways and Means Chairman Bill Thomas and Committee on Energy and Commerce Chairman Billy Tauzin introduced H.R. 2473, the

"Medicare Prescription Drug and Modernization Act of 2003". (Identical language in the form of a report was released publicly June 13, 2003.) On June 17, 2003, H.R. 2473 was marked up by the full Committee on Ways and Means and ordered favorably reported by a vote of 25-15, after adopted amendments—including the Thomas amendment in the nature of a substitute—were accepted into the bill. The amendments that were accepted to the Thomas amendment in the nature of a substitute were: (1) an amendment offered by Mrs. Johnson to instruct the Secretary of the U.S. Department of Health and Human Services to promptly evaluate existing codes for physician services associated with the administration of covered outpatient drugs; and to use existing processes to establish relative values for such services; (2) an en bloc amendment offered by Mr. Collins to exempt MA private FFS plans from compliance with the drug utilization management program, negotiation of discounts from manufacturers, disclosure of fact that generic drug is available at a lower cost, and TRICARE standards for participation; and (3) an amendment offered by Mr. Nussle and Mr. Pomeroy to adjust the Medicare inpatient hospital prospective payments system wage index to revise the labor-related share of such index, and to provide a five percent bonus payment to physicians operating in physician scarcity areas.

II. EXPLANATION OF PROVISIONS

A. TITLE I – MEDICARE PRESCRIPTION DRUG BENEFIT

Section 101. Establishment of a Medicare Prescription Drug Benefit.

Current Law

Medicare does not cover most outpatient prescription drugs. Beneficiaries in hospitals or skilled nursing facilities may receive drugs as part of their treatment. Medicare payments made to the facilities cover these costs. Medicare also makes payments to physicians for drugs or biologicals that are not usually self-administered. This means that coverage is generally limited to drugs or biologicals administered by injection. However, if the injection is generally self-administered (e.g., insulin), it is not covered.

Despite the general limitation on coverage for outpatient drugs, Medicare statute specifically authorizes coverage for the following: (1) drugs used in immunosuppressive therapy (such as cyclosporin) following discharge from a hospital for a Medicare-covered organ transplant, (2) erythropoietin (EPO) for the treatment of anemia for persons with chronic renal failure who are on dialysis, (3) drugs taken orally during cancer chemotherapy provided they have the same active ingredients and are used for the same indications as chemotherapy drugs which would be covered if they were not self-administered and were administered as incident to a physician's professional service, and (4) hemophilia clotting factors for hemophilia patients competent to use such factors to control bleeding without medical supervision, and items related to the administration of such factors. The program also pays for supplies (including drugs) that are necessary for the effective use of covered durable medical equipment, including those that must be put directly into equipment (e.g., tumor chemotherapy agents used with an infusion pump). Medicare also covers pneumococcal pneumonia vaccines, hepatitis B vaccines, and influenza virus vaccines.

Explanation of Provision

The provision would establish a new voluntary prescription drug benefit program under a new Medicare Part D of Title XVIII of the Social Security Act. Effective January 1, 2006, a new voluntary benefit would be established. Beneficiaries could purchase either "standard coverage" or actuarially equivalent coverage approved by the Secretary of Health and Human Services. In 2006, "standard coverage" would have a $250 deductible, 80 percent coverage for costs between $251 and $2,000, and all costs after the individual has borne $3,500 in out-of-pocket spending (a.k.a. the catastrophic threshold). The catastrophic threshold would be raised for individuals with income above $60,000 and couples with income above $120,000. Subsidies would be provided for persons with income below 150 percent of poverty. Coverage would be provided through PDPs, Medicare Advantage (MA) plans (formerly known as Medicare+Choice plans), or Enhanced Fee-For-Service plans (EFFS). The program would rely on private plans to provide coverage and to bear some of the financial risk for drug costs. Federal subsidies would be provided to encourage participation. Plans would be expected to negotiate prices for drugs. A

new Medicare Benefits Administration (MBA), within the Department of Health and Human Services (HHS), would contract with plans.

New Section 1860D-1. Benefits; Eligibility; Enrollment; and Coverage Period.

The new Section 1860A would specify that each individual entitled to Medicare Part A or enrolled in Medicare Part B would be entitled to obtain qualified prescription drug coverage under Medicare. MA plans and EFFS plans (MA-EFFS plans) would be required to offer qualified prescription drug coverage. An individual enrolled in a MA-EFFS plan would obtain their drug coverage through the plan. An individual not enrolled in either a Medicare Advantage or EFFS plan could enroll in a new PDP. The provision would specify that an individual eligible to make an election to enroll in a PDP, or with a MA-EFFS plan, would do so in accordance with regulations issued by the Administrator of the new MBA. Enrollments and changes in enrollment could occur only during a specified election period. The election periods would generally be the same as those established for MA-EFFS programs including annual coordinated election periods and special election periods. An individual discontinuing a MA election during the first year of eligibility would be permitted to enroll in a PDP at the same time as the election of coverage under the original fee-for-service plan (FFS).

An initial six month election period, beginning on October 1, 2005, would be established for persons entitled to Part A or enrolled under Part B on that date. For persons first entitled to Part A or enrolled in Part B after that date, an initial election period that would be the same as that for initial Part B enrollment, would be established. The MBA Administrator would be required to establish special election periods for persons in specific circumstances, such as having and then involuntarily losing prescription drug coverage; enrollment delays or non-enrollment attributable to government action; becoming eligible for Medicaid drug coverage; or any such exceptional circumstance specified by the MBA Administrator (including circumstances pertaining to MA enrollment).

Guaranteed issue and community-rating protections would be established for beneficiaries. Individuals electing qualified prescription drug coverage under a PDP plan or MA-EFFS plan could not be denied enrollment based on health status or other factor. MA provisions relating to priority enrollment (where capacity limits have been reached) and limitations on terminations of elections would apply to PDP sponsors.

The provision would specify that PDP sponsors and MA-EFFS organizations providing qualified prescription drug coverage could not deny, limit, or condition the coverage or provision of benefits or increase the premium based on any health-related status factor in the case of persons who maintained continuous prescription drug coverage since the date they first qualified to elect drug coverage under Part D. Individuals who did not maintain continuous coverage could be subject to an adjusted premium in a manner reflecting the additional actuarial risk involved. Such risk would be established through an appropriate actuarial opinion.

An individual would be considered to have had continuous prescription drug coverage if the individual could establish that he or she had coverage under one of the following (and coverage in one plan occurred no more than 63 days after termination of coverage in another

plan): (1) a qualified PDP or MA-EFFS plan, (2) Medicaid, (3) a group health plan, but only if benefits were at least equivalent to benefits under a qualified PDP, (4) a Medigap plan, but only if the policy was in effect on January 1, 2006, and only if the benefits were at least equivalent to benefits under a qualified PDP, (5) a state pharmaceutical assistance program, but only if benefits were at least equivalent to benefits under a qualified PDP, or (6) a veteran's plan, but only if benefits were at least equivalent to benefits under a qualified PDP. Individuals could apply to the MBA Administrator to waive the requirement that such coverage be at least equivalent to benefits under a qualified PDP if they could establish that they were not adequately informed that the coverage did not provide such level of coverage.

PDP sponsors would make drug coverage available to all eligible individuals residing in the area—without regard to their health, economic status, or place of residence.

Elections would take effect at the same time that they do for MA plans; however, no election could take effect before January 1, 2006. The MBA Administrator would provide for the termination of an election in the case of termination of Part A and Part B coverage or termination of an election for cause (including failure to pay the required premium).

New Section 1860D-2. Requirements for Qualified Prescription Drug Coverage.

The new Section 1860D-2 would specify the requirements for qualified prescription drug coverage. Qualified coverage would be defined as either "standard coverage" or actuarially equivalent coverage.

For 2006, "standard coverage" would have a $250 deductible, 80 percent coverage for costs between $251 and $2,000, and full coverage for all costs after the individual has borne $3,500 in out-of-pocket spending (a.k.a. the catastrophic threshold). Beneficiaries would have access to negotiated discounts even where there would be no insurance benefit (between $2,000 in spending and $3,500 in out-of-pocket spending). Beginning in 2007, standard coverage thresholds would be increased by the annual percent increase in average per capita expenditures for covered outpatient drugs for beneficiaries (for the 12-month period ending in July of the previous year).

Plans would be permitted to substitute cost-sharing schedules for costs up to the initial coverage limit ($2,000) that are actuarially consistent with the average expected 20 percent cost-sharing up to the initial coverage limit. They could also apply tiered coinsurance, provided such coinsurance was actuarially consistent with the average 20 percent cost-sharing requirements.

Costs that would count toward meeting the catastrophic limit would only be considered incurred if they were paid for the deductible, cost-sharing, or benefits not paid because of application to the initial coverage limit. Costs would be treated as incurred costs only if they are paid by the individual (or by another family member on behalf of the individual), paid on behalf of a low-income individual under the subsidy provisions, under the Medicaid program, or by a state pharmaceutical assistance program. Substantial new assistance would be provided to those states with pharmaceutical assistance programs through the catastrophic benefit by requiring

Medicare to pay 80 percent of the costs above the catastrophic limit. Any costs for which the individual was reimbursed by insurance or otherwise would not count toward incurred costs.

The provision would increase the annual out-of-pocket threshold for each enrollee whose adjusted gross income exceeds a specified income threshold. The portion of income exceeding this income threshold ($60,000 for individuals and $120,000 for couples in 2006), but below an income threshold limit ($200,000 in 2006), would be considered in making this calculation. The increase would be calculated as follows: first, the ratio of the annual out-of-pocket limit to the income limit would be calculated and expressed as a percent; for 2006, this would be $3,500 divided by $60,000, equaling about 5.8 percent. This percentage would be multiplied by income over the income threshold, not exceeding $140,000. Thus, the catastrophic out-of-pocket limit would be $5,820 for an enrollee with an income of $100,000 and $11,620 for persons with incomes at $200,000 or above. Beginning in 2007, the income threshold and income threshold limit would be increased by the percentage increase in the consumer product index (CPI) for all urban consumers, rounding to the nearest $100.

The amount used for making the income determination would be adjusted gross income Individuals filing joint returns would be treated separately with each person considered to have an adjusted gross income equal to one-half of the total. The determination would be the most recent return information disclosed by the Secretary of the Treasury to the Secretary of HHS before the beginning of the year. The Secretary, in coordination with the Secretary of the Treasury, would provide a procedure under which an enrollee could elect to use more recent information, including information for a taxable year ending in the current calendar year. Through the 1-800 toll free Medicare beneficiary line, individuals would have assistance in appealing a determination from the Medicare Ombudsman. The process would require: (1) the enrollee to provide the Secretary with the relevant portion of the more recent return, (2) verification by the Secretary of the Treasury, and (3) payment by the Secretary to the enrollee equal to the benefit payments that would have been payable under the plan if more recent information had been used. If such payments were made, the PDP sponsor would pay the Secretary the requisite amount, less the applicable reinsurance that would have applied.

The Secretary would be required to provide, through the annual Medicare handbook, general information on the calculation of catastrophic out-of-pocket thresholds. The Secretary would periodically transmit to the Secretary of the Treasury the names and Social Security Numbers (SSNs) of enrollees in PDPs or MA-EFFS plans and request that the Secretary of the Treasury disclose income information. The Secretary would disclose to entities offering the plan the amount of the out-of-pocket threshold that would apply to a specified taxpayer. New confidentiality protections and severe criminal and civil penalties would apply to any unauthorized disclosure of information.

The provision would permit a PDP or MA-EFFS sponsor to offer, subject to approval by the MBA Administrator, alternative coverage providing certain requirements were met. The actuarial value of total coverage would have to be at least equal to the actuarial value of standard coverage. The unsubsidized value of the coverage (i.e. the value of the coverage exceeding subsidy payments) would have to be equal to the unsubsidized value of standard coverage. The coverage would be designed (based on actuarially representative patterns of utilization) to

provide for payment of incurred costs up to the initial coverage limit of at least the same percentage of costs provided under standard coverage. Further, catastrophic protection would have to be the same as that under standard coverage. It could not vary.

Both standard coverage and actuarially equivalent coverage would offer access to negotiated prices, including applicable discounts. Access would be provided even when no benefits were payable because of the application of cost-sharing or initial coverage limits. Insofar as a State elected to use these negotiated prices for its Medicaid program, the Medicaid drug payment provisions would not apply. Further, the negotiated prices would not be taken into account in making "best price" determinations under Medicaid. Under the current Medicaid best price policy, the largest discount a pharmaceutical manufacturer negotiates in the private market must be passed along to the Medicaid program as well. Since manufacturers can only influence market share and volume in the private sector, not Medicaid, the "best price" policy has led to less discounting by manufacturers. As a result, arbitrary price floors are created and consumers pay the price as competing manufacturers have had less incentive to steeply discount their prices. This provision saves Medicare billions of dollars by encouraging pharmaceutical manufacturers to offer the same discounts that private plans currently receive. For transparency reasons, the PDP or MA-EFFS sponsor would be required to disclose to the MBA Administrator the extent to which manufacturer discounts or rebates or other remunerations or price concessions are made available to the sponsor or organization and passed through to enrollees through pharmacies. Manufacturers would be required to disclose pricing information to the MBA Administrator under the same conditions currently required for Medicaid. Transparency in pricing and rebate arrangements is a key factor in ensuring beneficiaries and taxpayers are receiving the best value for their resources.

Qualified prescription drug coverage could include coverage exceeding that specified for standard coverage or actuarially equivalent coverage. However, any additional coverage would be limited to covered outpatient drugs. The MBA Administrator could terminate a contract with a PDP or MA-EFFS sponsor if a determination was made that the sponsor or organizations engaged in activities intended to discourage enrollment of classes of eligible Medicare beneficiaries obtaining coverage through the plan on the basis of their higher likelihood of utilizing prescription drug coverage.

Covered outpatient drugs would be defined to include: (1) a drug which may only be dispensed subject to a prescription and which is described in subparagraph (A)(i) or (A)(ii) of Section 1927(k)(2) of the Social Security Act (relating to drugs covered under Medicaid), (2) a biological product described in paragraph B of such subsection, (3) insulin described in subparagraph C of such section, and (4) vaccines licensed under Section 351 of the Public Health Service Act. Drugs excluded from Medicaid coverage would be excluded from the definition except for smoking cessation drugs. The definition includes any use of a covered outpatient drug for a medically accepted indication. Drugs paid for under Medicare Part B would not be covered under Part D. A plan could elect to exclude a drug that would otherwise be covered, if the drug was excluded under the formulary and the exclusion was not successfully appealed under the new Section 1860D-3. In addition, a PDP or MA-EFFS sponsor could exclude from coverage, subject to reconsideration and appeals provisions, any drug that either does not meet Medicare's definition of medical necessity or is not prescribed in accordance with the plan or Part D.

Beneficiaries could appeal the placement of a drug in a higher coinsurance tier to an external, independent entity.

New Section 1860D-3. Beneficiary Protections for Qualified Prescription Drug Coverage.

The new Section 1860D-3 would specify required beneficiary protections. Plans would have to comply with guaranteed issue and community-rated premium requirements specified in the new Section 1860D-1, access to negotiated prices as specified in the new Section 1860D-2, and the non-discrimination provisions specified in the new Section 1860D-6.

The PDP sponsors would be required to disclose to each enrolling beneficiary information about the plan's benefit structure, including information on: (1) access to covered drugs, including access through pharmacy networks, (2) how any formulary used by the sponsor functioned, (3) copayment and deductible requirements (including any applicable tiered copayment requirements), and (4) grievance and appeals procedures. In addition, beneficiaries would have the right to obtain more detailed plan information. The sponsor would be required to make available, through an Internet site and, on request, in writing, information regarding the basis for exclusion of any drug from the formulary. Plans must notify enrollees when a change has been made in the preferred status of a drug or biological, or if there has been a change in a beneficiary's coinsurance. Plans would be required to furnish to enrollees a detailed explanation of benefits, including information on benefits compared to the initial coverage limit and the applicable out-of-pocket threshold.

PDP and MA-EFFS sponsors would be required to permit the participation of any pharmacy that met the plan's terms and conditions. Beneficiaries would be ensured access to any convenient local pharmacy that chose to participate in the plan. PDP and MA-EFFS sponsors could reduce coinsurance for their enrolled beneficiaries below the otherwise applicable level for drugs dispensed through in-network pharmacies; in no case could the reduction result in an increase in subsidy payments made by the MBA Administrator to the plan. Sponsors would be required to secure participation in its network of a sufficient number of pharmacies that dispense drugs directly to patients to assure convenient access. Mail order only pharmacy would be prohibited so that beneficiaries have access to a convenient bricks and mortar pharmacy. The MBA Administrator would establish convenient access rules that were no less favorable to enrollees than rules for convenient access established by the Secretary of Defense on June 1, 2003, for the TRICARE Retail Pharmacy program. The TRICARE standard specifies that, in an urban area, 90 percent of beneficiaries must be within two miles of a participating pharmacy; in a suburban area, 90 percent of beneficiaries must be within five miles of a participating pharmacy; and in rural areas, 70 percent of beneficiaries must be within fifteen miles of a participating pharmacy. According to the Department of Defense, the TRICARE Retail Pharmacy program receives minimal access complaints each year, and problems and disputes related to access are resolved quickly. The rules would include adequate emergency access for enrolled beneficiaries. Sponsors would permit enrollees to receive benefits through a community pharmacy, rather than through mail-order, with any differential in cost paid by enrollees. Pharmacies could not be required to accept insurance risk as a condition of participation. It is important that pharmacies are not put at risk for events they cannot control, such as volume and frequency of prescriptions.

PDP and MA-EFFS sponsors would be required to issue (and reissue as appropriate) a card or other technology that could be used by an enrolled beneficiary to assure access to negotiated prices for drugs when coverage is not otherwise provided under the plan. The MBA Administrator would provide for the development of uniform standards relating to a standardized format for the card or other technology. These standards would be compatible with the administrative simplification requirements of Title XI of the Social Security Act.

There is no requirement to use a formulary, however, if a PDP or MA-EFFS sponsor uses a formulary, it would have to meet certain requirements. It would be required to establish an independent pharmaceutical and therapeutic committee free of conflict with the plan to develop and review the formulary. The committee would include at least one physician and one pharmacist with expertise in the care of elderly or disabled persons, and the majority of members would be physicians or pharmacists. The committee would be required, when developing and reviewing the formulary, to base clinical decisions on the strength of scientific evidence and standards of practice, including assessing peer-reviewed medical literature, such as randomized clinical trials, pharmacoeconomic studies, outcomes research data, and such other information the committee determined appropriate. Arbitrary determinations to exclude products from the formulary would not be permitted.

The P&T committee would also take into account whether including a particular covered drug had therapeutic advantages in terms of safety and efficacy. In addition, the formulary would have to include at least two drugs within each therapeutic category and class of covered outpatient drugs, although not necessarily all drugs within such categories or classes. When establishing such classes, the committee would take into account the standards published in the United States Pharmacopoeia Drug Information. It would be required to make available to plan enrollees, through the Internet or otherwise, the clinical basis for the coverage of any drug on the formulary. The committee would be required to establish policies and procedures to educate and inform health care providers concerning the formulary. Any removal of a drug from the formulary could not occur until appropriate notice had been provided to beneficiaries and physicians. The plan would provide for periodic evaluation and analysis of treatment protocols and procedures. Further, the PDP or MA-EFFS sponsor would be required to provide for, as part of its overall appeals process, appeals of coverage denials regarding application of the formulary.

Each PDP or MA-EFFS sponsor would ensure that each pharmacy or other dispenser informed enrolled beneficiaries at the time of purchase, of any price differential between their prescribed drug and the price of the lowest cost generic drug covered under the plan that was therapeutically equivalent and bioequivalent.

The PDP or MA-EFFS sponsor would be required to have (directly, or indirectly through arrangements): (1) an effective cost and drug utilization management program, (2) quality assurance measures including a medication therapy management program, (3) for years beginning with 2007, an electronic prescription drug program, and (4) a program to control waste, fraud, and abuse. Utilization management programs would be required to include medically appropriate incentives to use generic drugs and therapeutic interchange where appropriate. Medication therapy management programs would be designed to assure, for beneficiaries at risk for potential medication problems such as beneficiaries with complex or

chronic diseases (such as diabetes, asthma, hypertension, and congestive heart failure) or multiple prescriptions, that drugs under the plan were appropriately used to optimize therapeutic outcomes through improved medication use and to reduce the risk of adverse events, including adverse drug interactions. The program would be developed in cooperation with licensed pharmacists and physicians. The PDP sponsor would be required, when establishing fees for pharmacists and other providers, to take into account the resources and time associated with the medication therapy management program. MA private fee-for-service plans would not be required to comply with the drug utilization management program, negotiate discounts from manufacturers, meet the TRICARE standards for participation, or disclose the fact that a lower priced generic drug is available at the time of purchase.

The electronic prescription drug program would have to be consistent with national standards developed by the MBA Administrator. The program would be required to provide for electronic transmittal of prescriptions (except in emergencies and exceptional cases) and for provision of information to the prescribing health professional. To the extent feasible, the program would permit the prescribing health professional to provide, and be provided, information on an interactive real-time basis. The electronic prescribing program would permit health professionals to access information on the different medications a senior may be taking – making it easier to prevent adverse drug interactions and side effects. In addition, electronic prescribing would cut down on both the costs and hassle that pharmacists incur trying to decipher a handwritten script. These systems will increase drug compliance and properly monitor drug utilization.

The MBA Administrator would be required to provide for the development of national standards relating to the electronic prescription drug program. The standards would be compatible with those established for the administrative simplification program established under title XI of the Social Security Act. The MBA Administrator would establish an advisory task force that included representatives of physicians, hospitals, pharmacies, beneficiaries, pharmacy benefit managers, technology experts, and pharmacy benefit experts of the Department of Veterans Affairs, Defense and other appropriate Federal agencies. The task force would provide recommendations to the MBA Administrator on standards including recommendations relating to: (1) range of available computerized prescribing software and hardware and their costs to develop and implement, (2) extent to which such standards and systems reduce medication errors and can be readily implemented by physicians, pharmacies, and hospitals, (3) efforts to develop uniform standards and a common software platform for the secure electronic transmission of medication history, eligibility, benefit and prescription information, (4) efforts to develop and promote universal connectivity and interoperability for the secure exchange of information, (5) cost of implementing such systems in hospital and physician office settings and pharmacies, and (6) implementation issues as they relate to administrative simplification requirements and current Federal and State prescribing laws and regulations and their impact on implementation of computerized prescribing. The MBA Administrator would be required to establish the task force by April 1, 2004. The task force would be required to submit recommendations to the MBA Administrator by January 1, 2005. The MBA Administrator would be required to promulgate national standards by January 1, 2006. Given current available technology, the committee supports the timely development of standards to facilitate a secure electronic prescription information program between prescribing health care professionals,

pharmacists, and pharmacy benefit managers (PBMs) to reduce dangerous drug interactions as well as errors due to poor handwriting and transcribing errors. To this end, the committee believes that it would be to the benefit of the patient for prescribing professionals to have real-time, "up-front" access to the patient's medication history, eligibility for benefits, drug formulary (if applicable), and coverage, when making prescribing decisions.

Each PDP sponsor would be required to have meaningful procedures for the hearing and resolving of any grievances between the organization (including any entity or individual through which the organization provides covered benefits) and enrollees. Enrollees would be afforded access to expedited determinations and reconsiderations, in the same manner afforded under MA. A beneficiary in a plan that provided for tiered cost-sharing could request coverage of a non-preferred drug on the same conditions applicable to preferred drugs if the prescribing physician determines that the preferred drug for the treatment of the same condition was not as effective for the enrollee or could have adverse effects for the enrollee. Such decisions could also be appealed under the MA appeals structure.

In general, PDP sponsors would be required to meet for independent review standards for coverage denials and appeals in the same manner that such standards apply to MA organizations. An individual enrolled in a PDP could appeal to obtain coverage for a drug not on the formulary or in a different cost sharing tier if the prescribing physician determined that the formulary drug for treatment of the same condition was not as effective for the individual or had adverse effects for the individual. The PDP sponsor would be required to meet requirements related to confidentiality and accuracy of enrollee records in the same manner that such requirements apply to MA organizations.

New Section 1860D-4. Requirements for and Contracts With Prescription Drug Plan (PDP) Sponsors.

New Section 1860D-4 would specify organizational plan requirements for entities seeking to become PDP sponsors. In general, the section would require a PDP sponsor to be licensed under state law as a risk-bearing entity eligible to offer health insurance or health benefits coverage in each state in which it offers a prescription drug plan. Alternatively it could meet solvency standards established by the MBA Administrator for entities not licensed by the state. Plans would be required to assume full financial risk on a prospective basis for covered benefits except: (1) as covered by federal subsidy payments and reinsurance payments for high-cost enrollees, or (2) as covered by federal incentive payments to encourage plans to expand service areas for existing plans or establish new plans. The entity could obtain insurance or make other arrangements for the cost of coverage provided to enrollees.

PDP sponsors would be required to enter into a contract with the MBA Administrator under which the sponsor agrees to comply both with the applicable requirements and standards and the terms and conditions of payment. The contract could cover more than one plan. The MBA Administrator would have the same authority to negotiate the terms and conditions of the plans as the Director of the Office of Personnel Management has with respect to FEHB plans. The MBA Administrator would be required to take into account subsidy payments for covered

benefits in negotiating the terms and conditions regarding premiums. The MBA Administrator would designate at least 10 service areas consistent with the areas established for EFFS plans.

The new section would incorporate, by reference, many of the contract requirements applicable to MA plans, including minimum enrollment, contract periods, allowable audits to protect against fraud and abuse, intermediate sanctions, and contract terminations. Pro rated user fees could be established to help finance enrollment activities; in no case could the amount of the fee exceed 20 percent of the maximum fee permitted for a MA plan.

The new Section would permit the MBA Administrator to waive the state licensure requirement under circumstances similar to those permitted under Part C for provider-sponsored organizations. In such cases, plans would be required to meet financial solvency and capital adequacy standards established by the MBA Administrator. The MBA Administrator would establish such standards by regulation by October 1, 2004.

The standards established under Part D would supersede any state law or regulation (other than state licensing laws or laws relating to plan solvency). In addition, states would be prohibited from imposing premium taxes or similar taxes with respect to premiums paid to PDP sponsors or payments made to such sponsors by the MBA Administrator.

New Section 1860D-5. Process for Beneficiaries to Select Qualified Prescription Drug Coverage.

The new Section 1860D-5 would require the MBA Administrator to establish a process for the selection of a PDP or MA-EFFS sponsor that provided qualified prescription drug coverage. The process would include the conduct of annual coordinated election periods under which individuals could change the qualifying plans through which they obtained coverage. The process would also include the active dissemination of information to promote an informed selection among qualifying plans (based on price, quality, and other features) in a manner consistent with and in coordination with the dissemination of information under MA. Further, the process would provide for the coordination of elections through filing with a PDP or MA-EFFS sponsor in a manner consistent with that provided under MA. The plan would have to inform each enrollee at the beginning of the year of the enrollee's annual out-of-pocket threshold.

The section would specify that an EFFS enrollee could only elect to receive drug coverage through the plan.

The MBA Administrator would assure that all eligible individuals residing in the United States would have a choice of enrollment in at least two qualifying plan options, at least one of which is a PDP, in their area of residence. The requirement would not be satisfied if only one PDP or MA-EFFS sponsor offers all the qualifying plans in the area. If necessary to ensure such access, the MBA Administrator would be authorized to provide partial underwriting of risk for a PDP sponsor to expand its service area under an existing prescription drug plan to adjoining or additional areas, or to establish such a plan, including offering such plan on a regional or nationwide basis. The assistance would be available only so long as, and to the extent necessary,

to assure the guaranteed access. However, the MBA Administrator could never provide for the full underwriting of financial risk for any PDP sponsor. Additionally, the MBA Administrator would be directed to seek to maximize the assumption of financial risk by PDP sponsors and entities offering MA-EFFS plans. The MBA Administrator would be required to report to Congress annually on the exercise of this authority and recommendations to minimize the exercise of such authority.

New Section 1860D-6. Submission of Bids.

The new Section 1860D-6 would require each PDP sponsor to submit to the MBA Administrator specified information in the same manner MA organizations submit information. The submitted information would be the qualified drug coverage to be provided, the actuarial value of the coverage, and details of the bid and coverage premium. The PDP sponsor would include: (1) actuarial certification of the bid and premium, (2) the portion of the bid and premium attributable to benefits in excess of the standard coverage, (3) the reduction in the premium resulting from reinsurance subsidies, (4) the reduction in the bid resulting from direct and reinsurance subsidy payments, and (5) such other information required by the MBA Administrator.

The MBA Administrator would review the submitted information for purposes of conducting negotiations with the plan. The MBA Administrator would approve the premium only if it accurately reflected the actuarial value of the benefits and the 73 percent average subsidy provided for under the new Section 1860D-8. The MBA Administrator would apply actuarial principles to approval of a premium in a manner similar to that used for establishing the monthly Part B premium. These requirements would not apply to MA plans.

The bid and premium for a PDP could not vary among individuals enrolled in the plan in the same service area, provided they were not subject to late enrollment penalties. A PDP sponsor would permit each enrollee to have their premiums withheld from their Social Security checks in the same manner as is currently done for Part B premiums and transferred to the plan in which they are enrolled. Beneficiaries could also make payment of the premium through an electronic funds transfer mechanism. The amount would be credited to the Medicare Prescription Drug Trust Fund. Reductions in Part B premiums attributable to enrollment in MA plans could be used to reduce the premium otherwise applicable.

Under certain conditions, PDP or MA-EFFS sponsors in an area would be required to accept, for an individual eligible for a low-income premium subsidy, the reference premium amount (premium for standard coverage) as payment in full for the premium for qualified prescription coverage. This requirement would apply if there was no standard coverage available in the area.

New Section 1860D-7. Premium and Cost-Sharing Subsidies for Low-Income Individuals.

The new Section 1860D-7 would provide subsidies for low-income individuals. Low-income persons would receive a premium subsidy (based on the value of standard coverage). Individuals with incomes below 135 percent of poverty (and assets below $4,000) would have a

subsidy equal to 100 percent of the value of standard drug coverage provided under the plan. For individuals between 135 percent and 150 percent of poverty, there would be a sliding scale premium subsidy ranging from 100 percent of such value at 135 percent of poverty to zero percent of such value at 150 percent of poverty. The asset test for this part is twice the asset test used for determining Supplemental Security Income (SSI) eligibility, indexed to inflation. (Note: the asset test has not previously been indexed.) Not all resources are counted. Excluded resources include: a home (with no limit on its value) if the individual lives in it; household goods and personal effects up to $2,000; one car used to provide necessary transportation regardless of value or if not used to provide transportation, excluded up to $4,500 in value; the value of a burial space; other property essential for self support of the individual; life insurance up to $1,500; the value of a trust, but trusts must meet very specific criteria; and other exclusions. Sponsors and entities could not charge individuals receiving cost-sharing subsidies more than five dollars per prescription. Sponsors and entities could reduce the cost-sharing to zero, which would otherwise be applicable for generic drugs.

State Medicaid programs or the Social Security Administration (SSA) would determine whether an individual would be eligible for a low-income subsidy, as well as the amount of the subsidy. SSA would be appropriated the necessary funds. The Congressional Budget Office (CBO) estimates that 152,000 seniors who would otherwise not enroll in the low-income subsidy program would participate since the enrollment process through SSA avoids the stigma of signing up at a welfare office. Individuals not in the 50 States or the District of Columbia could not be subsidy eligible individuals but could be eligible for financial assistance with drug costs under new Section 1935(e) added by Section 103.

Whether offered by a PDP or MA-EFFS sponsor, the premium subsidy amount would be defined as the benchmark premium amount for the qualified prescription drug coverage chosen by the beneficiary. The benchmark premium amount for a plan means the premium amount for enrollment under the plan (without regard to any subsidies or late enrollment penalties) for standard coverage (or alternative coverage if the actuarial value is equivalent). If a plan provides alternative coverage with a higher actuarial value than that for standard coverage, the benchmark amount would bear the same ratio to the total premium as the actuarial value of standard coverage was to the actuarial value of alternative coverage.

The MBA Administrator would provide a process whereby the PDP or MA-EFFS sponsor would notify an individual that he or she is eligible for a subsidy as well as the amount of the subsidy. The sponsor would reduce the individual's premium or cost-sharing otherwise imposed by the amount of the subsidy. The MBA Administrator would periodically, and on a timely basis, reimburse the sponsor or entity for the amount of such reductions.

Part D benefits would be primary to any coverage available under Medicaid. The MBA Administrator would be required to develop and implement a plan for the coordination of Part D benefits and Medicaid benefits. Particular attention would be given to coordination of payments and preventing fraud and abuse. The MBA Administrator would be required to involve the Secretary, the States, the data processing industry, pharmacists, pharmaceutical manufacturers, and other experts in the development and administration of the plan.

New Section 1860D-8. Subsidies for All Medicare Beneficiaries for Qualified Prescription Drug Coverage.

New Section 1860D-8 would provide for subsidy payments to qualifying entities. The payments would reduce premiums for all enrolled beneficiaries consistent with an overall subsidy level of 73 percent, reduce adverse selection among plans, and promote the participation of PDP sponsors. Such payments would be made as direct subsidies and through reinsurance. The section would constitute budget authority in advance of appropriations and represent the obligation of the MBA Administrator to provide for subsidy payments specified under the section.

Direct subsidies would be made for individuals enrolled in a PDP or MA-EFFS plan, equal to 43 percent of the national weighted average monthly bid amount. Each year, the MBA Administrator would compute a national average monthly bid amount equal to the average of the benchmark bid amounts for each drug plan (not including those offered by private plans) adjusted to add back in the value of reinsurance subsidies. The benchmark bid amount would be defined as the portion of the bid attributable to standard coverage or actuarial equivalent coverage. The bid amount would be a weighted average with the weight for each plan equal to the average number of beneficiaries enrolled in the plan for the previous year. (The MBA Administrator would establish a procedure for determining the weighted average for 2005).

Reinsurance payments would be made for specified costs incurred in providing prescription drug coverage for individuals enrolled in either a PDP or MA-EFFS plan. The MBA Administrator would provide for reinsurance payments to PDP sponsors, and entities offering MA or EFFS plans. Reinsurance payments would be provided for 30 percent of an individual's allowable drug costs over the initial reinsurance threshold ($1,000 in 2006) but not over the initial coverage limit ($2,000 in 2006). Reinsurance of 80 percent would also be provided for allowable costs over the out-of-pocket threshold ($3,500 in 2006). These reinsurance payments would provide additional assistance to those plans that enroll beneficiaries who have multiple or very expensive prescription drug regimens. In the aggregate, reinsurance payments would equal 30 percent of total payments made by qualifying entities for standard coverage.

For purposes of calculating reinsurance payments, allowable costs would be defined as the portion of gross covered prescription drug costs that were actually paid by the plan, but in no case more than the part of such costs that would have been paid by the plan if the drug coverage under the plan were standard coverage. Gross covered drug costs would be defined as costs (including administrative costs) incurred under the plan for covered prescription drugs dispensed during the year, including costs related to the deductible, whether paid by the enrollee or the plan, regardless of whether coverage under the plan exceeded standard coverage and regardless of when the payment for the drugs was made.

The MBA Administrator would be required to estimate the total reinsurance subsidy payments that would be made during the year (including those made to qualified retiree plans) and total benefit payments to be made by qualifying entities for standard coverage during the year. The MBA Administrator would proportionately adjust payments such that total subsidy

payments during the year were equal to 30 percent of total payments made by qualifying plans for standard coverage during the year. The MBA Administrator could adjust direct subsidy payments in order to avoid risk selection. The MBA Administrator would determine the payment method and could use an interim payment system based on estimates. Payments would be made from the Medicare Prescription Drug Trust Fund.

Special subsidy payments would be made to a qualified retiree prescription drug plan. A qualified plan would be defined as employment-based retiree health coverage (including coverage offered pursuant to one or more collective bargaining agreements) meeting certain requirements. The MBA Administrator would approve coverage with at least the same actuarial value as standard coverage. The sponsor (and the plan) would be required to maintain and provide access to records needed to ensure the adequacy of coverage and the accuracy of payments made. Further, the sponsor would be required to provide certifications of coverage. Payment could not be made for an individual unless the individual was covered under the retiree plan and entitled to enroll under a PDP or MA-EFFS plan but elected not to. Subsidy payments would equal 28 percent of allowable costs between $250 and $5,000. (The dollar amounts would be adjusted annually by the percentage increase in Medicare per capita prescription drug costs.)

About one-third of Medicare beneficiaries receive retiree coverage from their former employers. While most of these people are satisfied with their coverage, employers are under increasing pressure to drop or reduce prescription drug coverage. This subsidy provides employers and union plans with maximum flexibility, encouraging them to maintain or expand their retiree plans. Thus, Medicare would reap significant savings from subsidizing employer plans at two-thirds of the cost of other Medicare prescription drug plans.

New Section 1860D-9. Medicare Prescription Drug Trust Fund.

New Section 1860D-9 would create a Medicare Prescription Drug Trust Fund. Requirements applicable to the Part B trust fund would apply in the same manner to the Drug Trust Fund as they apply to the Part B Trust Fund. The Managing Trustee would pay from the account, from time to time, low-income subsidy payments, subsidy payments, and payments for administrative expenses. The Managing Trustee would transfer, from time to time, to the Medicaid account amounts attributable to allowable increases in administrative costs associated with identifying and qualifying beneficiaries eligible for low-income subsidies. Amounts deposited into the Trust Fund would include the federal amount which would otherwise be payable by Medicaid except for the fact that Medicaid becomes the secondary payer of drug benefits for the dual-eligibles. The provision would authorize appropriations to the Trust Fund an amount equal to the amount of payments from the Trust Fund reduced by the amount transferred to the Trust Fund.

The provision would specify that any provision of law relating to the solvency of the Trust Fund would take into account the amounts received by, or payable from, the Trust Fund.

Effective Date

Upon enactment.

New Section 1860D-10. Definitions; Treatment of References to Provisions in Part C.

New section 1860D-10 would include definitions of terms and specify how cross-references to Part C would be applied. It would further provide that any reduction or waiver of cost-sharing would not be in violation of kickback and similar prohibitions. The section would further require the Secretary to submit a report to Congress within 6 months of enactment that makes recommendations regarding providing benefits under Part D.

Also within six months of enactment, the Secretary would be required to review the current standards of practice for pharmacy services provided to patients in nursing facilities. Specifically, the Secretary would assess: (1) the current standards of practice, clinical services, and other service requirements generally utilized for such pharmacy services, (2) evaluate the impact of those standards with respect to patient safety, reduction of medication errors, and quality of care, and (3) recommend necessary actions.

Effective Date

Upon enactment.

Reason for Change

Prescription drugs are just as important to modern health care as hospitals and physician services were when Medicare was enacted in nearly 40 years ago. Prescription drugs are more often than not, the health care solution of choice. Most often, they prevent, treat or manage diseases more effectively and less invasively than hospitals and nursing homes. The typical senior now takes more than 20 prescriptions a year to improve their health or manage their diseases. While seniors are taking more drugs than any other demographic group, they are often paying the highest prices because more than one-third of seniors have no prescription drug coverage. Similarly, low-income beneficiaries must often make unacceptable choices between life-savings medicines and other essentials.

The addition of a prescription drug benefit to Medicare, while providing seniors additional choices in how they receive their health services, is a critical modernization of the program. In designing how these benefits are delivered, the Committee believes competition among plans will lead to the most efficient allocation of resources and will create opportunities to increase the availability of certain drugs, to reduce the cost of drugs, and the cost of the program to taxpayers.

Importantly, guaranteeing issuance of policies, providing uniform plan premiums, ensuring two plans in each area and providing a worst case fall back ensure beneficiaries have the coverage to which they are entitled. Important new beneficiary protections, such as allowing any willing pharmacy to participate, ensuring convenient access to bricks and mortar pharmacies, creating a level playing field for mail order and retail pharmacy, and prohibiting plans from pushing insurance risk onto pharmacists ensure seniors can get the drugs at the pharmacy of their

choice. Establishing new appeal rights for coverage denials or tiered cost sharing problems helps beneficiaries access the drugs most appropriate to their medical condition.

In addition, by providing new tools to improve health, such as electronic prescribing, medication therapy management, and utilization review, the provision would greatly improve the quality of services provided to beneficiaries.

In combination, these provisions will provide important new benefits where Medicare is lacking, create new choices for seniors, and create new protections to achieve the goals of reduced costs and improved health.

Section 102. Offering of Qualified Prescription Drug Coverage Under the Medicare Advantage and Enhanced Fee-For-Service Program.

Current Law

Under current law, Medicare+Choice plans may elect to offer prescription drug coverage under Part C. The extent of these benefits varies and is not subject to any explicit standardization requirements. However, as with all Medicare+Choice benefit specifics, the financing and design of such benefits must meet the approval of the Secretary under the adjusted community rate (ACR) approval process. Generally, plans offering drugs must either finance such benefits from the differences between the applicable county payment rate and their costs in providing Medicare's basic benefits, or by assessing beneficiaries who enroll in the plan supplemental premiums.

Explanation of Provision

The provision would specify that, beginning January 1, 2006, a MA organization could not offer a coordinated care MA plan unless either that plan or another plan offered by the organization in the area included qualified drug coverage. It could not offer drug coverage (other than that already required under Medicare) unless the coverage was at least qualified prescription drug coverage. An individual not electing qualified prescription drug coverage under Part D would be treated as ineligible to enroll in a MA plan offering such coverage.

The organization would be required to meet beneficiary protections outlined in the new Section 1860D-3, including requirements relating to information dissemination and grievance and appeals. The organization would also be required to submit the same information required of PDP sponsors when submitting a bid. The MBA Administrator could waive such requirements to the extent the MBA Administrator determined they were duplicative of requirements otherwise applicable to the organization or plan. MA organizations providing qualified drug coverage would receive low-income subsidy payments, and direct and reinsurance subsidies. A single premium would be established for drug and non-drug coverage.

The same requirements would be applicable to an EFFS organization.

Effective Date

Applies to coverage provided on or after January 1, 2006

Reason for Change

Ensures MA-EFFS plans offer qualified prescription drug coverage if they offer coverage, consistent with Section 101.

Section 103. Medicaid Amendments.

Current Law

Some low-income aged and disabled Medicare beneficiaries are also eligible for full or partial coverage under Medicaid. Within broad federal guidelines, each state sets its own eligibility criteria, including income eligibility standards. Persons meeting the state standards are entitled to full coverage under Medicaid. Persons entitled to full Medicaid protection generally have all of their health care expenses met by a combination of Medicare and Medicaid. For these "dual-eligibles" Medicare pays first for services both programs cover. Medicaid picks up Medicare cost-sharing charges and provides protection against the costs of services generally not covered by Medicare, including prescription drugs. State Medicaid programs have the option to include prescription drugs in their Medicaid benefit packages. All states include drugs for at least some of their Medicaid beneficiaries and many offer it to all program recipients entitled to full Medicaid benefits.

Federal law specifies several population groups that are entitled to more limited Medicaid protection. These are qualified Medicare beneficiaries (QMBs), specified low-income Medicare beneficiaries (SLMBs), and certain qualifying individuals. QMBs are aged or disabled persons with incomes at or below the federal poverty level and assets below $4,000 for an individual and $6,000 for a couple. QMBs are entitled to have their Medicare cost-sharing charges, including the Part B premium, paid by the federal-state Medicaid program. SLMBs are persons who meet the QMB criteria, except that their income is over the QMB limit; the SLMB limit is 120 percent of the federal poverty level. Medicaid protection for SLMBs is limited to payment of the Medicare Part B premium. QMBs and SLMBs are not entitled to Medicaid's prescription drug benefit unless they are also entitled to full Medicaid coverage under their state's Medicaid program.

Qualifying individuals (QIs) are never entitled to Medicaid drug coverage (because, by definition, they are not eligible for full Medicaid benefits). QI-1s are persons who meet the QMB criteria, except that their income is between 120 percent and 135 percent of poverty. Medicaid protection for QI-1s is limited to payment of the monthly Medicare Part B premium. QI-2s are persons who meet the QMB criteria, except that their income is between 135 percent and 175 percent of poverty. Medicaid protection for QI-2s is limited to payment of that portion of the Part B premium attributable to the gradual transfer of some home health visits from Medicare Part A to Medicare Part B. Expenditures under the QI-1 and QI-2 programs are paid for 100 percent by the Federal government (from the Part B Trust Fund) up to the state's

allocation level. A state is only required to cover the number of persons which would bring its spending on these population groups in a year up to its allocation level. Any expenditure beyond that level would be paid by the state. Assistance under the QI-1 and QI-2 programs is available for the period January 1, 1998 to December 31, 2002.

Explanation of Provision

Section 103 would add a new Section 1935 to the Social Security Act entitled "Special Provisions Relating to Medicare Prescription Drug Benefit." The provision requires states, as a condition of receiving Federal Medicaid assistance, to make eligibility determinations for low-income premium and cost-sharing subsidies, inform the MBA Administrator of cases where eligibility has been established, and otherwise provide the MBA Administrator with information that may be needed to carry out Part D. In 2005, the federal matching rate would be increased to 100 percent over 15 years. Beginning in 2020 the, the federal matching rate would be 100 percent. The states would be required to provide the MBA Administrator with the appropriate information needed to properly allocate administrative expenditures that could be made for similar eligibility determinations.

The provision would provide for the Federal phase-in of the costs of premiums and cost-sharing subsidies for dual-eligibles (i.e. persons eligible for Medicare and full Medicaid benefits, including drugs). Over the 2006 - 2020 period, the Federal matching rate for these costs would be increased to cover 100 percent of what would otherwise be state costs. States would be required to maintain Medicaid benefits as a wrap-around to Medicare benefits for dual-eligibles; states could require that these persons elect Part D drug coverage.

Residents of territories would not be eligible for regular low-income subsidies. However, territories would be able to get additional Medicaid funds, beginning at $25 million in 2006 and increasing in subsequent years by the annual percentage increase in prescription drug costs for Medicare beneficiaries. In order to obtain these funds, territories would be required to formulate a plan on how they would dedicate the funds to assist low-income Medicare beneficiaries in obtaining covered outpatient prescription drugs. The MBA Administrator would be required to report to Congress on the application of the law in the territories.

Effective Date

Upon enactment.

Reason for Change

Seniors should be treated as seniors first and low-income second. The patchwork of state Medicaid programs that can vary from state to state is confusing and demoralizing for many seniors. By federalizing the drug costs of the dual eligibles, we ensure beneficiaries have access to a uniform, Medicare benefit.

Section 104. Medigap Transition.

Current Law

Most beneficiaries have some health insurance coverage in addition to basic Medicare benefits. Some individuals obtain private supplemental coverage through an individually purchased policy, commonly referred to as a "Medigap" policy. Beneficiaries with Medigap insurance typically have coverage for Medicare's deductibles and coinsurance; they may also have coverage for some items and services not covered by Medicare. Individuals generally select from one of ten standardized plans, though not all ten plans are offered in all states. The plans are known as Plans A through plan J. Plan A covers a basic package of benefits. Each of the other nine plans includes the basic benefits plus a different combination of additional benefits. Plan J is the most comprehensive. Plans H, I, and J offer some drug coverage.

The law provided for the development by the National Association of Insurance Commissioners (NAIC) of standardized benefit packages. It also provides for modifications of such packages when Medicare benefit changes are enacted.

All insurers offering Medigap policies are required to offer open enrollment for 6 months from the date a person first enrolls in Medicare Part B (generally when the enrollee turns 65). The law also guarantees issuance of specified Medigap policies for certain persons whose previous supplemental coverage was terminated. Guaranteed issue also applies to certain persons who elect to try out a managed care option under the Medicare+Choice plan program.

Explanation of Provision

The provision would prohibit, effective January 1, 2006, the issuance of new Medigap policies with prescription drug coverage. The prohibition would not apply to policies replacing another policy with drug coverage. Further, it would not apply to policies meeting new standards, or pre-standards, as outlined below. Beneficiaries could keep their existing H, I, and J plans.

The provision would guarantee issuance of a substitute Medigap policy for persons, enrolling in Part D, who at the time of such enrollment were enrolled in and terminated enrollment in a Medigap H, I, or J plan. The guaranteed enrollment would be for any of the Plans A through Plan G. The guarantee would apply for enrollments occurring in the new Medigap plan within 63 days of termination of enrollment in a Medigap H, I, or J plan. The insurer could not impose an exclusion based on a pre-existing condition for such individuals. Further, the insurer would be prohibited from discriminating in the pricing of such policy on the basis of the individual's health status, claims experience, receipt of health care or medical condition.

The provision would provide for the development by the NAIC of two new standardized Medigap plans and would outline the standards for these policies. The first new policy would have the following benefits (notwithstanding other provisions of law relating to core benefits): (1) coverage of 50 percent of the cost-sharing otherwise applicable (except coverage of

100 percent cost-sharing applicable for preventive benefits), (2) no coverage of the Part B deductible, (3) coverage of all hospital coinsurance for long stays (as in current core package), and (4) a limitation on annual out-of-pocket costs for Part A and Part B beneficiaries of $4,000 in 2005 (increased in future years by an appropriate inflation adjustment as specified by the Secretary). The second new policy would have the same benefit structure as the first new policy, except that: (1) coverage would be provided for 75 percent, rather than 50 percent, of cost-sharing otherwise applicable, and (2) the limitation on out-of-pocket costs would be $2,000, rather than $4,000. Both policies could provide for coverage of Part D cost-sharing; however, neither policy could cover the Part D deductible.

The NAIC would make recommendations to Congress on modernizing the Medigap market.

It is the Committee's intent that the offering of these new Medigap policies would be voluntary on the part of insurers, as is the case for all other Medigap standardized policies beyond plan type A, basic Medigap coverage.

Effective Date

Upon enactment.

Reason for Change

The two new Medigap policies would provide additional cost sharing for beneficiaries without first dollar coverage. This ensures beneficiaries have additional access to cover cost sharing for the new prescription drug benefit if they so choose.

Section 105. Medicare Prescription Drug Discount Card Endorsement Program.

Current Law

On July 12, 2001, the President announced a new national drug discount card program for Medicare beneficiaries. Under this program, CMS would endorse drug card programs that meet certain requirements. This program was intended to be an interim step until a legislative reform package, including both a drug benefit and other Medicare reforms, is enacted. Implementation of the drug discount card program was suspended by court action.

Explanation of Provision

The provision would require the Secretary or Administrator to establish a program to: (1) endorse prescription drug discount card programs that meet certain requirements, and (2) make available information on such programs to beneficiaries. The Secretary would begin operating the program within 90 days of enactment. The Secretary would provide for an appropriate transition and discontinuation at the time a drug benefit first becomes available under Part D.

Programs endorsed by the Secretary must meet certain requirements. Programs shall pass negotiated discounts on drugs to enrollees. Programs could not be limited to mail order drugs and must provide support services to educate patients and prevent adverse events. Programs must also provide, through the Internet or otherwise, information to enrollees that the Secretary deems necessary for beneficiaries to make informed choices among all endorsed programs. This information would include information on enrollment fees, prices charged to beneficiaries, and services offered under the program. Program sponsors would be required to demonstrate experience and expertise in operating such a program. The sponsor would also be required to have in place adequate procedures for quality assurance. The annual enrollment fee could not exceed $30 (which could be paid in whole or in part by states). Further, the program would be required to meet additional requirements identified by the Secretary to protect and promote the interest of Medicare beneficiaries, including requirements that assure that beneficiaries were not charged more than the lower of the negotiated retail price or the usual and customary price.

The Secretary would provide for the dissemination of information that compared the costs and benefits of available programs. This activity would be coordinated with the dissemination of educational information on MA plans. The Secretary would also oversee the endorsed programs' compliance with the requirements of this section, including verification of discounts, and services provided, the amount of dispensing fees, and audits. The Secretary would be required to provide, through the use of the Medicare toll-free number, for the receipt and response to inquiries and complaints. The Secretary would be required to revoke the endorsement of any program that no longer meets requirements or engages in false or misleading marketing practices. The provision would specify that a beneficiary could only be enrolled in one endorsed program at a time. A beneficiary could change enrollment after he or she has been enrolled in a plan for a minimum period specified by the Secretary.

The provision creates a two-year, temporary, transitional low-income assistance program. Medicare beneficiaries with incomes below 150 percent of poverty would be eligible for assistance in 2004 and 2005. The program provides additional funds in conjunction with the discount card to help low-income seniors purchase prescription drugs prior to the implementation of the drug benefit in 2006. The bill provides for $2 billion in 2004 and $3 billion in 2005.

Effective Date

Upon enactment.

Reason for Change

Immediate help for those without prescription drug coverage will provide a transition into the new Part D drug benefit while ensuring those who cannot afford prescription drugs receive assistance. In addition, drug discount cards can be up and running within 90 days, which will provide savings to seniors at retail between 10 and 20 percent, according to HHS. Discounts must be provided by both manufacturers and pharmacies and must be passed on to beneficiaries.

Section 106. Disclosure of Return Information for Purpose of Carrying Out Medicare Catastrophic Prescription Drug Program.

Current Law

Current law authorizes, under specified circumstances, the Secretary of the Treasury to disclose returns and return information for purposes other than tax administration.

Explanation of Provision

The provision would permit the Secretary of the Treasury, upon written request from the Secretary of the Department of Health and Human Services (HHS), to disclose to officers and employees of HHS specific information with respect to a specified taxpayer for a specific tax year. Information that could be disclosed would be taxpayer identification information and adjusted gross income, or, simply the income threshold limit specified under the new Part D ($200,000 in 2006). A specified taxpayer would be either: (1) an individual who had adjusted gross income for the year in question in excess of the income threshold specified in the new Part D ($60,000 per individual), or (2) an individual who elected to use more recent income information as permitted under Part D. Individuals filing joint returns would be treated separately, each considered to have an adjusted gross income equal to one-half of the total.

Officers and employees of HHS would be authorized to use tax return information only for administering the prescription drug benefit. HHS could disclose a beneficiary's determined annual out-of-pocket threshold to a beneficiary's PDP sponsor. The sponsor could use such information only for the purposes of administering the benefit.

Effective Date

Upon enactment.

Section 107. State Pharmaceutical Assistance Transition Commission.

Current Law

A number of states currently have programs to provide low-income persons, not qualifying for Medicaid, with financial assistance in meeting their drug costs. The state programs differ substantially in both design and coverage.

Explanation of Provision

The provision would establish a State Pharmaceutical Assistance Transition Commission to develop a proposal for dealing with the transitional issues facing state programs and participants due to implementation of the new Part D prescription drug program. The Commission, to be established on the first day of the third month following enactment, would include: (1) a representative of each governor from each state with a program that the Secretary identifies as having a benefit package comparable to or more generous than the new Part D,

(2) representatives from other states that have pharmaceutical assistance programs, as appointed by the Secretary, (3) representatives (not exceeding the total under (1) or (2) above) of organizations that represent interests of participants, appointed by the Secretary, (4) representatives of Medicare Advantage organizations; and (5) the Secretary or the Secretary's designee and other members specified by the Secretary. The Commission would develop the proposal in accordance with specified principles, namely: (1) protection of the interests of program participants in the least disruptive manner, (2) protection of the financial and flexibility interests of states so they are not financially worse off, and (3) principles of Medicare modernization outlined in Title II of the Act. It is the intent of the Committee that Medicare beneficiaries use one prescription drug card for their benefit. The Committee believes presenting beneficiaries with more than one card would be confusing and administratively inefficient.

The Commission would report to the President and Congress by January 1, 2005. The report would contain specific proposals including specific legislative or administrative recommendations, if any. The Commission would terminate 30 days later.

Effective Date

Upon enactment

Reason for Change

States, especially those with comprehensive pharmaceutical assistance programs, would benefit significantly. States would receive billions of dollars in assistance under the proposal, with the most help going to those states that have already provided pharmaceutical drug assistance to seniors. Since some states have initiated pharmaceutical assistance for low-income seniors, these states would reap the most savings, as Medicare would become the primary insurer for these beneficiaries. States have several options in relation to the new benefit. First, they could design their pharmacy programs to "wrap around" the Medicare drug benefit. Second, their pharmacy program could subsidize low-income individuals with costs between $2,000 and the $3,500 catastrophic benefit. This spending would count toward the catastrophic cap. Further, state pharmacy assistance programs could use money saved from the Medicare drug benefit to extend their assistance to persons with incomes above 150 percent of poverty. Finally, state pharmacy programs could work to encourage low-income individuals to enroll in a PDP, thereby creating a seamless transition from the perspective of the individual. Their cost-sharing still could not exceed $5 per prescription, and they could get the prescription drugs they need at a convenient pharmacy. From the beneficiary's perspective nothing will have changed.

It is difficult to foresee every issue that may impact states that have already provided substantial assistance to seniors. A State Pharmaceutical Assistance Transition Commission would be established under the bill. This commission would develop a proposal to address the unique transition issues facing these states.

B. TITLE II – MEDICARE ENHANCED FEE-FOR-SERVICE AND MEDICARE ADVANTAGE PROGRAMS; MEDICARE COMPETITION

Section 200. Medicare Modernization and Revitalization.

Current Law

Health Maintenance Organizations (HMOs) and other types of managed care plans have been allowed to participate in the Medicare program, beginning with private health plan contracts in the 1970s and the Medicare risk contract program in the 1980s. BBA 97 replaced the risk contract program with the Medicare+Choice (M+C) program.

Explanation of Provision

This title would establish the Medicare Enhanced Fee-for-Service (EFFS) program, under which Medicare beneficiaries would be provided access to a range of EFFS plans that may include preferred provider networks. It would establish a Medicare Advantage (MA) program to offer improved managed care plans with coordinated care. It would also use competitive bidding, in the same style as FEHBP for certain areas, beginning in 2010, to promote greater efficiency and responsiveness to Medicare beneficiaries.

Effective Date

Upon enactment.

Reason for Change

This title modernizes and revitalizes private plans under Medicare. BBA 97 altered payments for private plans and expanded the types of plans that could be offered under Medicare. Since payment rate changes were implemented, enrollment in private plans has fallen from 6.2 million beneficiaries in 1998 to 4.6 million beneficiaries in May 2003, and the number of plans has decreased from 346 risk plans in 1998 to 153 (149 coordinated care plans and 4 private FFS plans) in May 2003. This disruption has been due, in part, to unpredictable and insufficient payments. BBA 97 fundamentally de-linked payments to plans from FFS payment growth.

To increase beneficiary choice, Title II reforms the payment system in 2004. All plans would be paid at a rate at least as high as the rate for traditional FFS Medicare, as recommended by the Medicare Payment Advisory Commission (MedPAC). After 2004, private plans' capitation rates would grow at the same rate as FFS Medicare. To increase beneficiary choice in more rural areas, Title II would establish the Enhanced Fee-for-Service (EFFS) program, which would encourage private plans to serve Medicare beneficiaries in larger regions, beginning in 2006. Private plans in both Medicare Advantage (MA) and EFFS plans would bid competitively against a benchmark beginning in 2006.

Once private plans became established, and enrollment in private plans increased, plans in certain areas would enter a FEHBP-style competitive bidding program, beginning in 2010. Plan bids from private plans and rates for traditional FFS Medicare would be averaged to create a benchmark for competitive bidding. The competitive program would encourage beneficiaries to enroll in the most efficient plan, producing savings for both beneficiaries, through reduced premiums, and for taxpayers, through relatively lower Medicare costs.

Subtitle A - Medicare Enhanced Fee-For-Service Program

Section 201. Establishment of Enhanced Fee-For-Service (EFFS) Program under Medicare.

Current Law

Payment. Under current law, Medicare+Choice (M+C) plans are paid an administered monthly payment, called the M+C payment rate, for each enrollee. The per capita rate for a payment area is set at the highest one of three amounts, calculated according to formulas established in statute and updated by law. The three amounts are:

- A minimum payment (or floor) rate,
- A rate calculated as a blend of an area-specific (local) rate and a national rate, or
- A rate reflecting a minimum increase from the previous year's rate.

After preliminary M+C payment rates are determined for each payment area (typically a county), a budget neutrality adjustment is required by law to determine final payment rates. This adjustment is made so that estimated total M+C payments in a given year would be equal to the total payments that would be made if payments were based solely on area-specific rates. The budget neutrality adjustment may only be applied to the blended rates because rates cannot be reduced below the floor or minimum increase amounts. The blend payment is also adjusted to remove the costs of direct and indirect graduate medical education. The blend payment amount is based on a weighted average of local and national rates for all Medicare beneficiaries. Blend payments have been made only once since 1998 (in the year 2000) because of the budget neutrality provision.

Each year, the three payment amounts are updated by formulas set in statute. Both the floor and the blend are updated each year by a measure of growth in program spending per capita, the national growth percentage. The minimum increase provides an additional two percent over the previous year's amount.

Eligibility: Medicare beneficiaries who are entitled to Medicare Part A and are enrolled in Part B may receive benefits through traditional FFS or they may enroll in a M+C plan.

Explanation of Provision

Beginning January 1, 2006 the MBA Administrator would establish an EFFS program to offer EFFS plans to EFFS-eligible individuals in one of not less than 10 regions established by the MBA Administrator. Before establishing regions, the MBA Administrator must conduct a market survey and analysis to determine how regions should be established.

The EFFS plans would be required to provide open network plans -- either Fee-for-Service (FFS) or preferred provider coverage. Under FFS coverage, plans would: (1) reimburse hospitals, physicians and other providers at a rate determined by the plan on a FFS basis, without placing providers at financial risk, (2) not vary rates based on utilization related to the provider, and (3) not restrict the selection of providers from among those who are lawfully authorized to provide covered services and agree to accept the plan's terms and conditions. Preferred Provider Organization (PPO) coverage plans would: (1) require a network of providers who agreed to a contractually specified reimbursement for covered benefits with the organization, and (2) provide for reimbursement for all covered benefits regardless of whether they were provided within the network.

The EFFS-eligible individuals would be those individuals who were entitled to Medicare Part A and enrolled in Part B. EFFS plans could only be offered in a region, if the plan was: (1) available to all EFFS beneficiaries in an entire region, (2) complied with statutory access requirements, (3) uniformly provided all required Parts A and B benefits, and other benefits as may be required, (4) included a single deductible for benefits under Parts A and B, and a catastrophic limit on out-of-pocket expenses, and (5) provided prescription drug coverage for each enrollee electing Part D drug coverage. The MBA Administrator would not approve an EFFS plan if benefits were designed to substantially discourage enrollment by certain eligible individuals.

Each year, beginning in 2006, an EFFS organization would submit a monthly bid amount for each plan in each region, referred to as the "EFFS monthly bid amount". The bid could not vary among EFFS eligible individuals in the EFFS region involved. The EFFS organization would be required to provide the following information: (1) the bid amount for the provision of all required items and services, based on average costs for a typical enrollee residing in the region and the actuarial basis for determining such amount, (2) the proportion of the bid attributed to the provision of statutory non-drug benefits (the "unadjusted EFFS statutory non-drug monthly bid amount"), statutory prescription drug benefits, and non-statutory benefits, (3) the actuarial basis for determining these proportions, and (4) additional information as the MBA Administrator may require. The MBA Administrator would have the negotiation authority that the Director of the Office of Personnel Management has with regard to FEHBP to negotiate the bid amount and could also reject a bid amount or proportion, if it was not supported by the actuarial basis. The MBA Administrator could enter into contract for up to three EFFS plans in any region.

Certain plans, based in part on their monthly bid amount, may be able to provide beneficiary savings. The EFFS plan would provide the enrollee a monthly rebate equal to 75 percent of the average per capita savings, if any. (Calculation of average per capita savings is

discussed below.) The rebate could be in the form of a credit towards the EFFS monthly prescription drug premium or the EFFS monthly supplemental beneficiary premium, a direct monthly payment, or other means approved by the MBA Administrator.

The MBA Administrator would determine, at the same time payment rates were announced (beginning in 2006), the average of the risk adjustment factors, by region. For plans offered in the previous year, the MBA Administrator could compute the average based on a previous year's risk adjustment factors. For plans entering a region, in which no plan was offered in the previous year, the MBA Administrator would estimate the average, and could use factors applied in comparable regions or on a national basis.

For each EFFS plan, the MBA Administrator would adjust the EFFS region -specific non-drug monthly benchmark amount and the unadjusted EFFS statutory non-drug monthly bid amount by the applicable average risk adjustment factor. The average per capita monthly savings would equal the amount by which the risk-adjusted benchmark exceeds the risk-adjusted bid. The EFFS region-specific non-drug monthly benchmark amount would be an amount equal to 1/12 of the average (weighted by the number of EFFS-eligible individuals in each payment area) of the annual capitation rate calculated for that area.

The MBA Administrator would pay plans as follows. For plans with bids below the benchmark (for which there were average per capita monthly savings), the payment would equal the unadjusted EFFS statutory non-drug monthly bid amount, with three adjustments. Payment would be adjusted for demographics factors including age, disability, gender, institutional status, health status, and other factors; (2) intra-regional geographic variations; and (3) the amount of the monthly rebate for the plan and year. For plans with bids at or above the benchmark (for which there were no average per capita monthly savings), the payment amount would equal the EFFS region-specific non-drug monthly benchmark amount, with the demographic, health status and geographic adjustments. Additionally, for an EFFS enrollee who enrolls in Part D and elects qualified prescription drug coverage through the plan, the plan would receive reimbursement for prescription drugs. This reimbursement would include a direct subsidy payment, a reinsurance subsidy payment and reimbursement for premiums and cost-sharing reductions for certain low-income individuals.

Beneficiary EFFS premiums are defined as follows. In the case where a plan provides a rebate, the EFFS monthly basic beneficiary premium would be zero. In the case where a plan does not provide a rebate (the plan's unadjusted EFFS statutory non-drug bid is above the EFFS region specific non-drug benchmark), the EFFS monthly basic beneficiary premium would be the difference between the bid and the benchmark amount. The EFFS monthly prescription drug beneficiary premium would be the portion of the plan's total monthly bid that the statutory drug benefit represents. The EFFS monthly supplemental beneficiary premium would be the portion of the plan's total monthly bid that is attributable to the supplemental non-statutory benefits.

Most of the statutory requirements concerning payment rules (other than the requirements for rates, service areas and MSA payments), organization and financial requirements, the establishment of standards, and contracts, would apply to EFFS plans. However, unlike current law, EFFS plans would not be permitted to segment a region. No Medicare supplemental policy

could provide coverage of the single deductible or more than 50 percent of the other cost-sharing imposed under an EFFS plan under Part E.

Effective Date

On or after January 1, 2006.

Reason for Change

The EFFS program would encourage the development of regional plans, by requiring EFFS plans to serve all beneficiaries throughout the region. Because enrollees in an EFFS plan must have the same benefits, cost-sharing obligations, and premiums, EFFS would decrease the variation in private plan offerings in the M+C program today. EFFS plans would also encourage plans to enter rural areas, where few M+C plans currently exist.

In carrying out these programs, the Committee believes the existing experience of the Medicare Quality Improvement Organizations (QIOs) would be employed to offer assistance to beneficiaries, providers and plans operating in Parts C, D and E, particularly as it relates to quality improvement. QIOs are currently required to offer assistance with clinical improvement under Parts A and B in hospitals, physicians' offices, nursing homes and home health agencies and to all MA organizations under part C. Expanding the QIOs' work to include the new entities and benefits created in this legislation will help improve the quality of care for Medicare beneficiaries.

Subtitle B - Medicare Advantage Program

CHAPTER 1 - Implementation of Program

Section 211. Implementation of Medicare Advantage Program.

Current Law

Health Maintenance Organizations (HMOs) and other types of managed care plans have been allowed to participate in the Medicare program, beginning with private health plan contracts in the 1970s and the Medicare risk contract program in the 1980s. BBA 97 replaced the risk contract program with the Medicare+Choice (M+C) program.

Explanation of Provision

This provision would establish the Medicare Advantage (MA) program under Part C of Medicare, replacing the Medicare+Choice provision.

Effective Date

Upon enactment.

Reason for Change

Medicare Advantage would reform Medicare+Choice to increase beneficiary choice.

Section 212. Medicare Advantage Improvements.

Current Law

Payment. Under current law, Medicare+Choice (M+C) plans are paid an administered monthly payment, called the M+C payment rate, for each enrollee. The per capita rate for a payment area is set at the highest one of three amounts, calculated according to formulas established in statute and updated by law. The three amounts are:

- A minimum payment (or floor) rate,
- A rate calculated as a blend of an area-specific (local) rate and a national rate, or
- A rate reflecting a minimum increase from the previous year's rate.

After preliminary M+C payment rates are determined for each payment area (typically a county), a budget neutrality adjustment is required by law to determine final payment rates. This adjustment is made so that estimated total M+C payments in a given year would be equal to the total payments that would be made if payments were based solely on area-specific rates. The budget neutrality adjustment may only be applied to the blended rates because rates cannot be reduced below the floor or minimum increase amounts. The blend payment is also adjusted to remove the costs of direct and indirect graduate medical education. The blend payment amount is based on a weighted average of local and national rates for all Medicare beneficiaries. Blend payments have been made only once since 1998 (in the year 2000) because of the budget neutrality provision.

Each year, the three payment amounts are updated by formulas set in statute. Both the floor and the blend are updated each year by a measure of growth in program spending per capita, the national growth percentage. The minimum increase provides an additional two percent over the previous year's amount.

Eligibility: Medicare beneficiaries who are entitled to Medicare Part A and are enrolled in Part B may receive benefits through the traditional FFS program or they may enroll in a M+C plan.

Explanation of Provision

This provision would change payments for MA plans. A fourth payment option would be added: 100 percent of the adjusted FFS rate for the area (the Adjusted Average Per Capita Cost (AAPCC) for the year, for the MA payment area for services covered under Parts A and B for individuals entitled to benefits under Part A, enrolled under Part B, and who are not enrolled in a MA plan). The AAPCC would be adjusted to include the additional payments that would have been made if Medicare beneficiaries had not received services from facilities of the Department of Veterans Affairs (VA) and the Department of Defense (DoD), and would include payments for indirect medical education costs. The minimum payment (floor) would be increased as under

current law. The minimum percentage increase amount would also be changed. For 2004 and beyond, the minimum percent increase would be the greater of: (1) a two percent increase over the previous year, as under current law, or (2) the annual MA capitation rate for the area for the previous year, increased by the national per capita growth percentage increase. There would be no adjustment to the national growth percentage for prior years' errors before 2004, for purposes of calculating the minimum percentage increase in 2004. For 2005, the annual rate would equal the previous year's rate increased by the greater of two percent or the national per capita growth percentage.

No later than 18 months after enactment of this legislation, the Medicare Payment Advisory Commission would report to Congress providing an assessment of the method used for determining the adjusted average per capita cost (AAPCC). The report would examine: (1) the variation in costs between different areas, including differences in input prices, utilization and practice patterns, (2) the appropriate geographic area for payment, and (3) the accuracy of the risk adjustment methods in reflecting differences in the cost of providing care.

No later than July 1, 2006, the MBA Administrator would submit a report to Congress that describes the impact of additional financing provided under this Act and other Acts, including the Balanced Budget Refinement Act of 1999 (BBRA) and the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) on the availability of MA plans in different areas and its impact on lowering premiums and increasing benefits under such plans.

Effective Date

Upon enactment.

Reason for Change

In some M+C payment areas, the M+C payment rate is lower than the costs of providing FFS care to enrollees in traditional Medicare. Many private plans have seen their Medicare payment rates rise much less rapidly than the costs of FFS Medicare, as they have been held to increases of two percent annually every year since 1998, except for 2001 when a three percent increase was paid due to the BIPA. Health costs in general are running much higher than the two percent payment increases that most plans are receiving in the areas where most of the beneficiaries are enrolled in Medicare+Choice. Plans find it difficult—if not impossible—to contract with providers if FFS Medicare can reimburse providers at higher rates than private plans may offer, given their Medicare payments. If paid less than FFS Medicare, private plans may be forced to increase enrollee premiums or cost-sharing, or decrease supplemental benefits, such as prescription drug coverage. Since 1998, the number of plans participating in M+C has declined from 346 to 153. To level the playing field between traditional Medicare and private plans, under this provision all private plans would be paid at a minimum of the FFS rate. In addition, private plan rates would increase at the same rate as growth in FFS Medicare. The goal is to increase beneficiary choice, by increasing private plan participation in Medicare.

CHAPTER 2 - Implementation of Competition Program

Section 221. Competition Program Beginning in 2006.

Current Law

See Section 200. *Medicare Modernization and Revitalization* and Section 201. *Establishment of Enhanced Fee-For-Service (EFFS) Program under Medicare*.

Explanation of Provision

Each year, beginning in 2006, an MA organization would be required to provide the following information: (1) the bid amount for the provision of all required items and services, based on average costs for a typical enrollee residing in the area and the actuarial basis for determining such amount, (2) the proportion of the bid attributed to the provision of statutory non-drug benefits (the "unadjusted MA statutory non-drug monthly bid amount"), statutory prescription drug benefits, and non-statutory benefits, (3) the actuarial basis for determining these proportions, and (4) additional information as the MBA Administrator may require. The MBA Administrator would have the negotiation authority that the Director of the Office of Personnel Management has with regard to the FEHBP to negotiate the bid amount and could also reject a bid amount or proportion, if it was not supported by the actuarial basis. Private fee-for-service (PFFS) plans would be exempt from this negotiation and rejection.

Certain plans, based in part on their monthly bid amount, may be able to provide beneficiary savings. The MA plan would provide the enrollee a monthly rebate equal to 75 percent of the average per capita savings, if any, as discussed below. The rebate could be in the form of a credit towards the MA monthly supplemental beneficiary premium or the MA monthly prescription drug premium, a direct monthly payment, or other means approved by the MBA Administrator.

The MBA Administrator would determine, at the same time payment rates were announced (beginning in 2006), the average of the risk adjustment factors, by state, or on a basis other than the state. For plans offered in the previous year, the MBA Administrator could compute the average based on the previous year's risk adjustment factors. For plans entering a state, in which no plan was offered in the previous year, the MBA Administrator would estimate the average, and could use factors applied in comparable states or on a national basis.

For each MA plan, the MBA Administrator would adjust the FFS area-specific non-drug monthly benchmark amount and the unadjusted MA statutory non-drug monthly bid amount by the applicable average risk adjustment factor. The average per capita monthly savings would equal the amount by which the risk-adjusted benchmark exceeds the risk-adjusted bid. The FFS area-specific non-drug monthly benchmark amount would be an amount equal to 1/12 of the annual MA capitation rate calculated for that area.

Beginning in 2006, the MBA Administrator would pay plans as follows. For plans below the benchmark (for which there were average per capita monthly savings), the payment would

equal the unadjusted MA statutory non-drug monthly bid amount, with two adjustments. Payment would be adjusted for demographic factors including age, disability, gender, health status, and other factors, and the amount of the monthly rebate for the plan and year. For plans with bids at or above the benchmark (for which there were no average per capita monthly savings), the payment amount would equal the FFS area-specific non-drug monthly benchmark amount, with the demographic and health status adjustments. Additionally, for an MA enrollee who enrolls in Part D and elects qualified prescription drug coverage through the plan, the plan would receive reimbursement for prescription drugs. This reimbursement would include a direct subsidy payment, a reinsurance subsidy payment and reimbursement for premiums and cost-sharing reductions for certain low-income individuals.

The MBA Administrator would not approve a plan if benefits were designed to discourage enrollment by certain MA-eligible individuals. The MA monthly bid amount, the MA monthly basic and supplemental beneficiary premium and the MA monthly MSA premium, would not vary among individuals enrolled in the plan.

Effective Date

On or after January 1, 2006.

Reason for Change

Competitive bidding against a benchmark would encourage plans to become more efficient, in order to lower their bids and gain market share. Beneficiaries, because they would benefit from enrolling in plans with lower bids by receiving 75 percent of the difference between the plan's bid and the benchmark, would be encouraged to enroll in more efficient plans. Plan efficiency and beneficiary enrollment in more efficient plans would reduce the costs of Medicare, easing the threat to insolvency of the Medicare Part A Trust Fund and easing the taxpayers' burden. Indeed, the Congressional Budget Office has estimated that the increased benchmarks are fully paid for through the 25 percent savings to the government. The government would share in the savings as beneficiaries make rational and efficient choices.

CHAPTER 3 - Additional Reforms

Section 231. Making Permanent Change in Medicare Advantage Reporting Deadlines and Annual, Coordinated Election Period.

Current Law

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188) made temporary changes to reporting dates and deadlines: (1) the plan deadline for submitting adjusted community rates (ACRs) and other information moved from no later than July 1 to no later than the second Monday in September for 2002, 2003, and 2004, (2) the annual coordinated election period moved from the month of November to November 15 through December 31 for 2002, 2003, and 2004, and (3) the M+C payment rate announcement moved

from no later than March 1 to no later than the second Monday in May for 2003 and 2004. The Secretary is required to mail information to enrollees at least 15 days before each annual open season, including a list of plan and plan options.

Explanation of Provision

This provision would permanently: (1) move the plan deadline for submitting information to the second Monday in September; (2) change the annual coordinated election period to November 15 through December 31, and (3) move the annual payment rate announcement to no later than the second Monday in May. The requirement for providing information comparing plan options would be amended to require that the information would be provided to the extent possible at the time of preparation of material for mailing.

Effective Date

Upon enactment.

Reason for Change

The deadlines for reporting and election periods were moved to allow for more accurate information from both CMS and plans. As these dates were shifted to later in the year, consistent changes were made to allow for the annual open season for beneficiary enrollment in private plans. A provision was added to limit CMS' responsibility for mailing to only those materials available at the time of the mailing.

Section 232. Avoiding Duplicative State Regulations.

Current Law

Medicare law currently preempts State law or regulation from applying to M+C plans to the extent that they are inconsistent with Federal requirements imposed on M+C plans, and specifically, relating to benefit requirements, the inclusion or treatment of providers, and coverage determinations (including related appeals and grievance processes).

Explanation of Provision

This provision would stipulate that Federal standards established by this legislation would supersede any state law or regulation (other than state licensing laws or state laws relating to plan solvency), with respect to MA plans offered by MA organizations.

Effective Date

Upon enactment.

Reason for Change

This clarifies that the MA program is a Federal program operated under Federal rules. State laws, do not, and should not apply, with the exception of state licensing laws or state laws related to plan solvency. There has been some confusion in recent court cases. This provision would apply prospectively; thus, it would not affect previous and ongoing litigation.

Section 233. Specialized Medicare Advantage Plans for Special Needs Beneficiaries.

Current Law

One model for providing a specialized M+C plan, EverCare, operates as a demonstration program. EverCare is designed to study the effectiveness of managing acute-care needs of nursing home residents by pairing physicians and geriatric nurse practitioners. EverCare receives a fixed capitated payment, based on a percentage of the adjusted average per capita costs (AAPCC), for all nursing home resident Medicare enrollees.

Explanation of Provision

This provision would establish a new MA option – specialized MA plans for special needs beneficiaries (such as the EverCare demonstration). Special needs beneficiaries are defined as those MA-eligible individuals who are institutionalized, entitled to Medicaid, or meet requirements determined by the Secretary. Enrollment in specialized MA plans could be limited to special needs beneficiaries until January 1, 2007. No later than December 31, 2005 the MBA Administrator would be required to submit a report to Congress that assesses the impact of specialized MA plans for special needs beneficiaries on the cost and quality of services provided. No later than 6 months after enactment of this Act, the Secretary would be required to issue final regulations to establish requirements for special needs beneficiaries.

Effective Date

Upon enactment.

Reason for Change

Specialized MA plans for special needs beneficiaries are designed to serve beneficiaries with certain needs, thus these plans are not meant to handle beneficiaries without special needs. This provision allows these plans to serve beneficiaries for whom their programs were designed.

Section 234. Medicare MSAs.

Current Law

BBA 97 authorized a demonstration to test the feasibility of medical savings accounts (MSA) for the Medicare population. This M+C option is a combination of a health insurance plan with a large deductible and an M+C MSA. Contributions to an M+C MSA may be made annually from the enrollee's capitation rate after the plan's insurance premium has been paid. These contributions, as well as account earnings, are exempt from taxes. Withdrawals used to pay unreimbursed enrollee medical expenses are exempt from taxes if they would be deductible under the Internal Revenue Code. New enrollment is not allowed after 2003, or after the number of enrollees reaches 390,000, if earlier.

Explanation of Provision

This provision would permanently extend Medicare MSAs and remove the enrollment cap. It would eliminate the requirement that Medicare MSA plans report on enrollee encounters since MSAs are not plans but bank accounts. Non-contract providers furnishing services to enrollees of MSAs would be subject to the same balanced billing limitations as non-contract providers furnishing services to enrollees of coordinated care plans.

Effective Date

Upon enactment.

Reason for Change

Medicare MSAs are not being offered in the Medicare program today, despite the legislative authority granted in 1997 and despite the fact that non-Medicare MSAs are being offered. By eliminating the cap on enrollment, the time constraint, and the reporting requirements, the Committee hopes to encourage this additional choice for seniors.

Section 235. Extension of Reasonable Cost Contracts.

Current Law

Medicare reimburses cost-based plans for the actual cost of furnishing covered services, less the estimated value of beneficiary cost-sharing. The Secretary may not extend or renew a reasonable cost reimbursement contract for any period beyond December 31, 2004.

Explanation of Provision

This provision would allow reasonable cost contracts to be extended or renewed indefinitely, with an exception that would begin January 1, 2008. These contracts could not be extended or renewed for a service area, if during the entire previous year, the area had 2 or more

coordinated care MA plans or 2 or more EFFS plans which met the following minimum enrollment requirements: (1) at least 5,000 enrollees for the portion of the area within a metropolitan statistical area with a population of more than 250,000 and counties contiguous to such a metropolitan statistical area, and (2) at least 1,500 enrollees for any other portion of such area.

Effective Date

Upon enactment.

Reason for Change

The uncertainty about the continuation of cost contracts would be removed, allowing these plans to operate indefinitely, unless two other plans of the same type (i.e., either 2 MA or 2(c) EFFS plans) enter the cost contract's service area. If other plans are willing to enter the cost contract's service area, then the cost contract would be required to operate under the same provisions as these other private plans.

Section 236. Extension of Municipal Health Service Demonstration Projects.

Current Law

The Municipal Health Services Demonstration Project operates in four cities. These cities use their existing public health programs as the nucleus of a coordinated system to provide community-based health care for the underserved urban poor. The project provides comprehensive health services, including a prescription drug benefit and dental services.

BBA 97 extended the program through 2000. The BBRA extended it through 2002, and the BIPA extended it through December 31, 2004.

Explanation of Provision

This provision would extend the program until December 31, 2009, and permit the programs to enroll up to the number of individuals who were enrolled as of January 1, 1996.

Effective Date

Upon enactment.

Reason for Change

BBA 97 required demonstration participants to become M+C enrollees. In Baltimore, no M+C plans, and in the other, smaller sites, private sector options for Medicare beneficiaries are also limited. This provision also closed the program to new enrollees. The programs need a

certain number of enrollees to remain viable; opening enrollment with a cap at levels from 1996 would permit these programs to reach the enrollment levels they need to operate efficiently.

Subtitle C - Application of FEHBP-Style Competitive Reforms

Section 241. Application of FEHBP-Style Competitive Reform Beginning in 2010.

Current Law

See Section 200. *Medicare Modernization and Revitalization* and Section 201. *Establishment of Enhanced Fee-For-Service (EFFS) Program under Medicare*.

Explanation of Provision

Beginning in 2010, FEHBP-style competition would begin nationwide in competitive areas. Competitive areas are defined as areas in which Medicare beneficiaries have access to two private plans – either two MA or two EFFS plans – along with traditional FFS Medicare. Private plan enrollment in the area must be at least as great as private plan enrollment nationwide, or at least 20 percent. For example, if private plan enrollment nationwide is 15 percent, the area must have private plan enrollment of at least 15 percent to become a competitive area. If private plan enrollment nationwide is 40 percent, the area must have private plan enrollment of at least 20 percent to trigger competition. In addition, competitive MA (CMA) areas would be limited to metropolitan statistical areas, or areas with substantial numbers of MA enrollees. The two private plans must be offered during the open season by different organizations, and each must meet minimum enrollment requirements as of March of the previous year.

In competitive areas, private plans would submit bids and the MBA Administrator would calculate FFS amounts, based on the adjusted average per capita cost (AAPCC) in the area or region. The AAPCC would be adjusted to remove costs associated with direct graduate medical education, and to include costs of services provided to Medicare beneficiaries by VA and DoD military facilities. In addition, payments would be adjusted for health and other demographic factors.

The competitive benchmark would be set at the weighted average of the private plan bids and the FFS amount in the competitive area. In order to provide traditional FFS disproportionate influence in competitive areas, the weight of the benchmark for FFS would equal the nationwide proportion of Medicare beneficiaries enrolled in FFS, or the competitive area's proportion, if higher. The weights for all other private plans would equal the national proportion of beneficiaries enrolled in private plans, or the regional proportion if lower.

For the first 5 years of competition, the benchmarks for private plans would be a blend of the competitive benchmark and the older, pre-2010 benchmark. For the first year of competition, the private plan benchmark would be based 80 percent on the older benchmark and 20 percent on the newer benchmark. For the second year, the private plan benchmark would be based 60

percent on the older benchmark and 40 percent on the new benchmark. By the fifth year, the private plan's benchmark would be fully phased in, and equal the new competitive benchmark. This phase-in allows for a transition to a more competitive system based on the new competitive benchmark.

Premium adjustments for beneficiaries remaining in traditional FFS in competitive areas would also be phased-in over the first 5 years as a competitive area. The FFS amount would be compared to the new competitive benchmark. During the first year of competition, 20 percent of the change in beneficiary premiums would occur. During the second year of competition, 40 percent of the change would be implemented, and so forth, until 100 percent of the premium change would be implemented during the fifth year of competition.

Beneficiaries enrolling in plans with bids or FFS amounts below the competitive benchmark would receive 75 percent of the difference between the benchmark and bid/FFS amount, and the government would receive 25 percent of the difference. Beneficiaries enrolling in plans with bids/FFS amounts above the benchmark would pay the excess. Premium adjustments would be moderated over a 5-year period for beneficiaries remaining in traditional FFS in competitive areas. The traditional FFS beneficiary premium would be unaffected in non-competitive areas or regions.

Beginning in 2010, the MBA Administrator would announce the MA area-specific non-drug benchmark yearly. If applicable, the MBA Administrator would also announce, for the year and CMA area: the competitive MA non-drug benchmark; the national FFS market share percentage; the demographic, end-stage renal disease, and health status adjustment factors; the MA area-wide non-drug benchmark amount; the FFS area-specific non-drug amount; and MA enrollment.

To carry out this section, the MBA Administrator would transmit the name, social security number, and adjustment amount to the Commissioner of SSA at the beginning of each year and at periodic times throughout the year.

Effective Date

On or after January 1, 2010.

Reason for Change

Market-oriented policymakers have maintained that the best way to reform Medicare is to provide beneficiaries with a choice of plans, similar to the choice available to members of Congress under the Federal Employees Health Benefits Program (FEHBP). The Bipartisan Commission on the Future of Medicare came to the same conclusion.

Medicare must be transformed to bend the growth curve in expenditures to put the program on a sound financial footing. To reduce program growth, true competition, including both traditional fee-for-service and private plans, would begin in 2010 in certain competitive areas.

As areas of the country show increased enrollment in private plans, a more competitive system, based on the structure of the FEHBP, would provide for greater beneficiary savings and reductions in government costs. Allowing for competition for enrollees, between private plans and traditional FFS Medicare, would level the playing field between all options available to Medicare beneficiaries.

If traditional FFS Medicare is able to provide benefits at a lower cost than some or all private plans in a competitive area, then beneficiaries remaining in traditional FFS would see their premiums decline. In this case, beneficiaries enrolling in higher-cost private plans would be required to pay the extra price stemming from that decision. Likewise, if a private plan is able to offer Medicare beneficiaries coverage at a lower cost, then beneficiaries would be encouraged to enroll in the private plan by lowering the beneficiaries' costs of coverage under the private plan. In any case, beneficiaries would be entitled to the same defined benefit package and payments to plans would be fully adjusted for health and other demographic factors. If the traditional FFS plan disproportionately enrolls beneficiaries with poor risk, the beneficiary premium would be adjusted to compensate.

This reform is the only provision in the bill that has the potential to produce the savings needed for long-term solvency. Although the bill provides for bidding against a benchmark prior to 2010, the benchmarks prior to 2010 increase each year, by the rate of growth in Medicare. Without this stage of competition, private plans would not be able to influence the benchmark and would have an incentive to shadow price their benchmarks. A floating benchmark rewards more efficient plans, and it allows these more efficient plans to lower the benchmark and government outlays in future years, as their market share rises.

Several features were added in the Chairman's amendment in the nature of a substitute to allow for a smooth transition to a more competitive system in 2010 in competitive areas/regions, and to prevent shock to the current system. The competitive benchmark, based on private plan bids and traditional FFS rates, would be calculated based on the relative enrollment in FFS versus private plans nationwide (or the area/region if FFS enrollment is a larger proportion in the area/region). This feature ensures that the competitive benchmark is closer to the traditional FFS rate than would otherwise occur. Premium changes for beneficiaries remaining in traditional FFS in competitive areas would be phased-in over five years to prevent oscillations. In addition, the competitive benchmark would be phased-in over a 5-year period for private plans. This would allow for a more gradual change from the benchmarks under the pre-2010 system to the new competitive benchmark for private plans in competitive areas.

C. TITLE III - COMBATTING WASTE, FRAUD, AND ABUSE

Section 301. Medicare Secondary Payer (MSP) Provisions.

Current Law

In certain instances, Medicare is prohibited from making payment for a health care claim if payment is expected to be made promptly under a worker's compensation law or plan, under

automobile or liability insurance (including a self-insured plan), or under no-fault insurance on behalf of a beneficiary. Medicare is permitted to make a conditional payment in certain circumstances including if Medicare could reasonably expect payment to be made under a workers' compensation plan or no-fault insurance claim and Medicare determines that the payment will not be made promptly, as determined in accordance with regulations.

Explanation of Provision

The Secretary would be able to make a Medicare payment if a worker's compensation law or plan, an automobile or liability insurance policy or plan (including a self-insured plan), or a no-fault insurance plan, has not been made or cannot reasonably be expected to be made promptly (as determined in accordance with regulations). This payment would be contingent on reimbursement by the primary plan to the Medicare Trust Funds.

The list of primary plans for which conditional payment could be made would be expanded; an entity engaging in a business, trade, or profession would be deemed as having a self-insured plan if it carries its own risk. Failure to obtain insurance would be required as evidence of carrying risk. A primary plan, as well as an entity that receives payment from a primary plan, would be required to reimburse the Medicare Trust Funds for any payment made by the Secretary if the primary plan was obligated to make payment. The Secretary's authority to recover payment from any and all responsible entities and bring action, including the collection of double damages, to recover payment under the Medicare Secondary Payer provisions also would be clarified.

Effective Date

Subsection (a) would be effective as if included in the enactment of Title III of the Medicare and Medicaid Budget Reconciliation Amendments of 1984 (P.L. 98-369). Subsection (b) would be effective upon enactment.

Reason for Change

Recent court decisions such as *Thompson v. Goetzmann* resulted in a narrow interpretation of the statutory reference to "promptly." Liability insurers would have been able to draw out their settlements and avoid repaying Medicare for payment of medical expenses. Moreover, firms that self-insure for product liability would have been able to avoid paying Medicare for past medical payments related to the claim. This provision guards the Medicare trust fund and saves nearly nine-billion dollars over 10 years.

Section 302. Competitive Acquisition of Certain Items and Services.

Current Law

In general, durable medical equipment (DME) is paid for under a set of local (or state) fee schedules subject to certain floors and ceilings as well as limited to the lower of the actual charge for the equipment or the fee schedule amount. Fee schedule amounts received an update of the full consumer price index for urban consumers (CPI-U) in 2003.

BBA 97 authorized the Secretary to conduct up to five demonstration projects to test competitive bidding as a way for Medicare to price and pay for Part B services other than physician services. The Secretary was required to establish up to three competitive acquisition areas for this purpose. Three competitive bidding demonstrations for durable medical equipment, prosthetics, orthotics, and supplies were successfully implemented: two in Polk County, Florida and one in the San Antonio, Texas area.

Explanation of Provision

The Secretary would be required to establish and implement competitive acquisition programs for durable medical equipment, medical supplies, items used in infusion, drugs and supplies used in conjunction with durable medical equipment, parenteral nutrition, and off-the-shelf orthotics (requiring minimal self-adjustment for appropriate use) that would replace the Medicare fee schedule payments. Class III devices—devices that sustain or support life, are implanted, or present potential unreasonable risk (e.g. implantable infusion pumps and heart valve replacements)— are subject to premarket approval by the Food and Drug Administration and would not be covered by the competitive bidding system.

In starting the competitive bidding programs, the Secretary would be required to establish competitive acquisition areas, but would be able to exempt rural areas and areas with low population density within urban areas that are not competitive, unless a significant national market exists through mail order for a particular item or service. The programs would be phased-in over three years with one-third of the areas implemented each year. High-cost and high-volume items and services would be required to be phased-in first. The Secretary would be able to exempt items and services for which competitive acquisition would not likely result in significant savings. The Secretary would be required to establish a process where existing rental agreements for covered DME items entered into contract before implementation of this program would not be affected. The supplier would be required to provide for appropriate servicing and replacement of these rental items.

Certain requirements for the competitive acquisition program would be established. Specifically, the Secretary would be allowed to award contracts in an area only when the following conditions were met: entities met quality and financial standards specified by the Secretary or the Program Advisory and Oversight Committee; total amounts paid under the contracts would be expected to be less than would be paid otherwise; and beneficiary access to multiple suppliers would be maintained. Beneficiary liability would be reduced to 20 percent of the applicable contract award price.

Contracts would be required to be re-competed at least every three years. The Secretary would be required to award contracts to multiple entities submitting bids in each area for an item or service and would also have the authority to limit the number of contractors in a competitive acquisition area to the number needed to meet projected demand for covered items and services. The Secretary would be permitted to waive certain provisions of the Federal Acquisition Regulation that are necessary for the efficient implementation of this program, other than those relating to confidentiality of information. The Secretary would be required to report to Congress

annually on savings, reductions in cost-sharing, access to items and services, and beneficiary satisfaction under the competitive acquisition program.

A Program Advisory and Oversight Committee with members appointed by the Secretary would be established. The Committee would be required to provide advice and technical assistance to the Secretary regarding the implementation of the program, data collection requirements, proposals for efficient interaction among manufacturers and distributors of the items and services, providers, and beneficiaries, and other functions specified by the Secretary. The provisions of the Federal Advisory Committee Act would not apply to this Committee.

The Secretary would be required to conduct a demonstration program on using competitive acquisition for clinical laboratory tests that are furnished without a face-to-face encounter between the individual and the hospital personnel or physician performing the tests. The same quality and financial conditions specified for the DME competitive acquisition program would apply for clinical laboratory test competitive acquisition. An initial report to Congress would be required of the Secretary and must be submitted by December 31, 2005 with progress and final reports, as the Secretary would determine appropriate. The General Accounting Office (GAO) would be required to report to Congress on the differences in reimbursement between public and private payors of clinical diagnostic services. The Secretary would be required to study whether suppliers of DME are soliciting physicians to prescribe certain brands or modes of delivery of covered items based on profitability.

The covered items and services included in the competitive acquisition program would be paid as determined under this program. The Secretary would be able to use this payment information to adjust the payment amounts for DME not located in a competitive acquisition area. In this instance, the inherent reasonableness rule would not be applied. Orthotics included in a competitive acquisition program would also be paid the amounts determined by this program. The Secretary would be able to use this payment information to adjust the payment amounts for such items. In this instance, the regular payment rules established by regulation, including the inherent reasonableness rule, would not be applied.

Effective Date

Upon enactment.

Reason for change

Numerous studies conducted by the HHS Office of the Inspector General (OIG) as well as GAO have found the government-determined fee schedule for durable medical equipment (DME) too high for certain items. For example, the OIG found that Medicare's reasonable payment methodology paid too much for parenteral nutrition. The OIG also found that Medicare payments for hospital beds were substantially higher than rates paid by other payors. Further, the OIG discovered that payments for albuterol were six times the catalog price for the drug.

The DME competitive bidding demonstration has been a success. The taxpayers and beneficiaries saved significantly and quality standards were higher under the demonstration.

More, that three-quarters of the DME winners were small businesses and beneficiary satisfaction remained high.

Section 303. Competitive Acquisition of Covered Outpatient Drugs and Biologicals.

(a) Adjustment to the Physician Fee Schedule.

Current Law

The relative value associated with a particular physician service is the sum of three components: physician work, practice expense, and malpractice expense. Practice expense includes both direct costs (such as clinical staff time and medical supplies used to provide a specific service to an individual patient) as well as indirect costs such as rent, utilities, and business costs associated with running a practice. When the physician fee schedule was implemented, reimbursement for practice expenses was based on historic charges. The Social Security Act Amendments of 1994 (PL. 103-432) required the Secretary to develop a methodology for a resource-based system for calculating practice expenses for use in CY1998. BBA 97 delayed the implementation of the methodology until CY1999 and established a transition period with full implementation by CY2002. BBRA required the Secretary to establish a data collection process and data standards for determining practice expense relative values. Under this survey process, the Secretary was required to use data collected or developed outside HHS, to the maximum extent practicable, consistent with sound data collection practices.

The Secretary is required to periodically review and adjust the relative values affecting physician payment to account for changes in medical practice, coding changes, new data on relative value components, or the addition of new procedures. Under the budget-neutrality requirement, changes in these factors cannot cause expenditures to differ by more than $20 million from what would have been spent if such adjustments had not been made.

Explanation of Provision

As part of the annual process of establishing the physician fee schedule, the Secretary would be required to increase the practice expense relative values using supplemental survey data provided by entities and organizations. This survey data must meet the Secretary's criteria for acceptance and include expenses for the administration of drugs and biologicals.

The Secretary would be directed to cooperate with representatives of physician specialties affected by reform of the Average Wholesale Price (AWP) method of reimbursement for outpatient prescription drugs. The Secretary would be required to expedite consideration of the Current Procedural Terminology (CPT) codes used to bill for the costs associated with the administration of outpatient drugs affected by AWP reform. In addition, the Secretary would be required to consult with representatives of advisory physician groups, such as the Practice Expense Advisory Committee, when reviewing CPT codes.

Increases in practice expenses resulting from the use of new survey data submitted by the date of enactment, or consideration of CPT codes for drug administration services for drugs affected by AWP reform would not be subject to the budget neutrality. The Secretary would not be prevented from adjusting the practice expense relative values in subsequent years. The Secretary would be required to consult with GAO and groups representing the affected physician specialties before publishing the notice of proposed rulemaking.

The resulting adjustments in practice expense relative value units would not be subject to administrative or judicial review. They would be considered as a change in law and regulation for purposes of determining the sustainable growth rate, used to set the payment update for physician services.

The Secretary would be required to adjust the non-physician work pool methodology so that practice expense relative values for these services are not disproportionately reduced as a result of the above changes.

Any physician specialty would be permitted to submit survey data related to practice expenses through December 31, 2004. Budget neutrality would not be waived.

Effective Date

Upon enactment.

Reason for Change

Physicians would be paid appropriate amounts for the administration of outpatient drugs covered by Medicare. It is the Committee's intent that the Secretary should use the survey data submitted by the American Society of Clinical Oncologists (ASCO) since the data meets all requirements for inclusion. The Committee directs the Secretary to depart from typical procedures and not average new ASCO survey data on practice expenses with older survey data from the American Medical Associations' socioeconomic monitoring system data. The Committee also directs the Secretary not to alter the ASCO survey data by removing any responses, including outliers. The Committee intends that the Secretary use the new ASCO survey data in the Secretary's normal methodology for determining practice expenses.

Furthermore, it is the Committee's intent that the Secretary use current procedures for consideration of CPT codes and modifications to those codes. The provision directs the Secretary to work with specialties affected by AWP reform to ensure that CPT codes, which would permit appropriate payment for drug administration, are in place before AWP reform occurs.

(b) Payment Based on Competition.

Current Law

Although Medicare does not currently provide an outpatient prescription drug benefit, coverage of certain outpatient drugs is specifically authorized by statute. Specifically, under Medicare Part B, outpatient prescription drugs and biologicals are covered if they are usually not self-administered and are provided incident to a physician's services. Drugs and biologicals are also covered if they are necessary for the effective use of covered durable medical equipment, including those that must be put directly into equipment. In addition, Medicare will pay for certain self-administered oral cancer and anti-nausea drugs, erythropoietin (used to treat anemia), immunosuppressive drugs after covered Medicare organ transplants and hemophilia clotting factors. Vaccines for diseases like influenza, pneumonia, and hepatitis B are considered drugs and are covered by Medicare. Payments for covered outpatient drugs are made under Medicare Part B and are based on 95 percent of AWP. The term "AWP" is not defined in statute or regulation, but generally, AWP is intended to represent the average price used by wholesalers to sell drugs to their customers. It has been based on reported prices as published in industry reference publications or drug price compendia. There are no uniform criteria for reporting these numbers. Moreover, these reported prices do not reflect the discounts that manufacturers and wholesalers customarily offer to providers and physicians. To differing degrees, the published prices on which Medicare payment's are based are higher than the amounts actually paid to acquire a given prescription drug.

Since covered outpatient prescription drugs are Part B services, Medicare pays 80 percent of the recognized amount and the beneficiary is liable for the remaining 20 percent coinsurance amount, except in the case of vaccines where no beneficiary cost-sharing is imposed. Also, beneficiaries cannot be charged for any amounts in excess of the recognized payment amount.

Explanation of Provision

New sections 1847A and 1847B in Title XVIII of the Social Security Act would be established to provide physicians in the Medicare program with an annual choice between two payment and delivery systems: (1) a contractor who would deliver drugs to the physician and would be reimbursed on prices established through a competitive bidding process, or (2) the physician would be reimbursed for covered drugs at the Average Sales Price (ASP).

Under Section 1847A, the Secretary would be required to establish a competitive acquisition program to acquire and pay for covered outpatient drugs. Under this program, at least two contractors would be established in each competitive acquisition area (which would be defined as an appropriate geographic region) throughout the United States. Each year, a physician would be required to select contractors who would deliver covered drugs and biologicals to the physician. There would be two categories of drugs under this program: the oncology category (which would include drugs determined by the Secretary as typically primarily billed by oncologists or are otherwise used to treat cancer) that would be implemented beginning in 2005, and the non-oncology category that would be implemented beginning in 2006. In this case, covered drugs means certain drugs currently covered under Section 1842(o)

of the Social Security Act which are not covered as part of the competitive acquisition for durable medical equipment. Blood clotting factors, erythropoetin furnished as treatment for end-stage renal disease (ESRD), and radiopharmaceuticals would not be considered covered drugs under the competitive acquisition program. Nothing in the section would affect the carrier invoice pricing method used to pay for radiopharaceuticals. The Secretary would also be able to exclude other drugs and biologicals or classes of drugs and biologicals that are not appropriate for competitive bidding or would not produce savings.

Certain contractor selection and contracting requirements for the competitive acquisition program would be established. Specifically, the Secretary would be required to establish an annual selection process for contractors in each area for each of the two categories of drugs. The Secretary may not award the two-year contract to any entity that does not have the capacity to supply covered outpatient drugs within the applicable category, or does not meet quality, service, or financial performance and solvency standards established by the Secretary. Specifically the contractor would be required to have: (1) arrangements to ship covered drugs at least 5 days of the week and on an emergency basis, (2) procedures for the prompt response and resolution of physician and beneficiary complaints and inquiries, and (3) grievance resolution procedures, including review by the Medicare Provider Ombudsman established in this legislation. At the Secretary's discretion, the Secretary could refuse to contract with an entity that has had its license for distributing drugs (including controlled substances) suspended or revoked by the Federal or a State government or that has been excluded from Medicare program participation. A contractor would be required to comply with a specified code of conduct, including conflict of interest provisions and all applicable provisions relating to the prevention of fraud and abuse. A contract would include specifications to ensure secure facilities, safe and appropriate storage of covered drugs, maintain record keeping, provide written policies and procedures to ensure drug safety, and retain compliance personnel. Either the Secretary or the entity could terminate contracts with appropriate advance notice. The Secretary would make the list of the available contractors accessible to physicians on an ongoing basis, through a directory posted on the Internet and provided by request.

The Secretary would be able to limit the number of qualified entities in each category and area, but not below two. The Secretary would be required to base selection on bid prices for covered drugs, bid prices for distribution of those drugs, ability to ensure product integrity, customer service, past experience with drug distribution, and other factors. Drugs dispensed under this program would be acquired directly from the manufacturer or from a distributor directly from the manufacturer. Contractors may be required to comply with additional product integrity safeguards for drugs susceptible to counterfeiting or diversion. The bid prices in an area would be effective for that area throughout the two-year contract period, but the contract would allow for appropriate price adjustments to reflect significant increases or decreases in a contractor's reasonable, net acquisition costs as disclosed to the Secretary. The Secretary would not be able to accept a contract for an area if its aggregate average prices exceed 120 percent of the Average Sales Price established under 1847B. Under the program, the Secretary would be required to compute an area average of the submitted bid prices. For drugs and biologicals for which an average bid price has not been established due to its establishment as a new Medicare covered product, the payment rate would be the payment rate established under 1847B. The Secretary would be able to establish average sales price as the reimbursement amount in other

exceptional cases. Beneficiary liability would be limited to 20 percent of the payment basis for the covered drug or biological, and would be collected by the contractor upon drug administration.

The Secretary would be permitted to waive certain provisions of the Federal Acquisition Regulation that are necessary for the efficient implementation of this program, other than those relating to confidentiality of information. The contractor supplying the physician in the area would submit the claim for the drug and would collect the cost-sharing amount from the beneficiary after administration of the drug. Both program payment and beneficiary cost sharing amounts would only be made to the contractor; would only be made upon the administration of the drug; and would be based on the average bid of prices for the drug and biological in the area. The Secretary would be required to establish a process for recovery of payments billed at the time of dispensing for drugs that were not actually administered.

The appropriate contractor, as selected by the physician, would supply covered drugs directly to the physician, except under the circumstances when a beneficiary is able to receive a drug at home. The Secretary would be able to specify other non-physician office settings where a beneficiary would be able to receive a covered drug directly. However, the contractor would not be able to deliver drugs to a physician without first receiving a prescription as well as other necessary information specified by the Secretary. A physician would not be required to submit a prescription for each individual treatment. The Secretary would establish requirements, including adequate safeguards against fraud and abuse and consistent with safe drug practices, in order for a physician to maintain an inventory of drugs in cases where: the drugs or biologicals are immediately required, where the physician could not have reasonably anticipated the immediate requirement, where the contractor could not deliver the product in a timely manner, and in emergency situations related to the patient's health. No applicable State requirements relating to the licensing of pharmacies would be waived.

Current rules related to physician assignment and beneficiary appeal rights in cases of medical necessity denial would remain unchanged. New physician appeal rights would be established similar to those provided to physicians who prescribe durable medical equipment or laboratory tests.

The Secretary would be required to establish an advisory committee to assist in the implementation of this program. The Secretary would be required to report to Congress on savings, reductions in cost-sharing, access to items and services, the availability of contractors as well as beneficiary and provider satisfaction under the competitive acquisition program. These reports would be due each year from 2005 through 2007.

The new section 1847B would establish an alternative choice for physician reimbursement for covered Part B drugs based on an Average Sales Price methodology (ASP). ASP is calculated for multiple source drugs based on the average of all sales net of volume discounts, prompt pay discounts, cash discounts, free goods to physicians, charge backs and rebates other than Medicaid rebates. For single source products, ASP is calculated using the above methodology or the Wholesale Acquisition Cost, which ever is lower. In an initial period for which sales data is not available, the Secretary may determine the amount payable under the

section without regard to the manufacturer's average sales price. In response to a public health emergency, the Secretary may use the wholesale acquisition cost instead of the average sales price until the price and availability of the drug has stabilized. Prices would be reported to the Secretary on a quarterly and confidential basis.

The Secretary would submit an annual report to the Congress on trends in average sales prices, administrative costs associated with compliance with this section, the total value of payments made under this section, and a comparison of the average manufacturer price reported under Medicaid with the average sales price. GAO would be required to assess the impact of this program on the delivery of services, particularly with respect to beneficiary access to drugs and the site of delivery. MedPAC would be required to submit to Congress specific recommendations with respect to payment for blood clotting factors in its 2004 annual report.

Effective Date

Upon enactment.

Reason for Change

The Balanced Budget Act of 1997 (BBA 97, P.L.105-33) specified that Medicare payment for covered outpatient prescription drugs would equal 95 percent of AWP. Law or regulation does not define AWP. Publishing organizations report AWPs provided by drug manufacturers. Medicare carriers use the published data to payment for Medicare covered drugs, but AWPs are not grounded in any real market transaction, and do not reflect the actual price paid by purchasers. Congress has long recognized AWP is a list price and not a measure of actual prices. Congress is now able to adopt an alternative basis for payment that will more accurately reflect actual acquisition costs for physicians. This will ensure that Medicare no longer bases its payments on prices that do not reflect prices otherwise available through market incentives and transactions.

AWP for a product is often far greater than the acquisition cost paid by suppliers and physicians. Some drug manufacturers use AWP to inflate payments made for drugs. As a result of abuses in the current system, beneficiaries are paying hundreds of millions of dollars in inflated co-payments every year. Medicare also pays upwards of one billion dollars in excess payments every year.

Some physicians assert that the overpayment for drugs covers underpayment for practice expenses. They contend that Medicare does not adequately reimburse them for the practice expenses associated with providing care in outpatient settings. This section reduces the overpayment for drugs and biologics, while increasing physician practice expenses.

Over the past 6 years, the OIG has issued a number of reports, all of which have reached the conclusion that Medicare and its beneficiaries pay too much for prescription drugs. The OIG studied the prices for 24 Medicare covered drugs that accounted for $3.1 billion of the $3.9 billion in Medicare drug expenditures in 1999. The OIG compared Medicare reimbursement to prices available to the physician/supplier community, the Department of Veterans Affairs, and

Medicaid. They found that Medicare and its beneficiaries would have saved substantial amounts of money on their coinsurance. The savings would have been $761 million a year by paying the actual wholesale prices available to physicians and suppliers. For each drug, Medicare paid more than the wholesale price available to physicians and suppliers.

Subsequently, the findings of the report were updated with more current drug pricing information and estimated that, of the $3.7 billion Medicare spent for 24 drugs in 2000, had Medicare paid the actual wholesale prices available to physicians and suppliers for these 24 drugs, the program and its beneficiaries would save $887 million a year. If Medicare had paid for these drugs based on catalog prices, according to the OIG, beneficiaries would have paid over $175 million less in coinsurance.

GAO's September 2001 report found that physicians can obtain Medicare-covered drugs at prices below current Medicare payments. In fact, wholesalers' and Group Purchasing Organizations' (GPO) prices are less than the AWP currently used to establish Medicare reimbursement for covered drugs. GAO found that the average discount from AWP ranged from 13 percent to 34 percent, and that two drugs had discounts of 65 percent and 86 percent.

In its recommendations to the Congress, the GAO urged CMS to take steps to begin reimbursing providers for part B-covered drugs and related services at levels reflecting providers' acquisition costs using information about actual market transaction prices. CMS should also evaluate expanding competitive bidding approaches to setting payment levels, according to the GAO, and that CMS should monitor beneficiary access to covered drugs in light of any changes to reimbursement.

The GAO also debunked some common myths generally held by many in the health care community. Specifically, the GAO found that despite concerns that the discounts available to large purchasers would not be available to physicians with a small number of drug claims, physicians with low volumes reported that their purchase prices were the same or less than the widely available prices GAO documented. GAO also believes that Medicare should pay for each service appropriately and not rely on overpayments for some services to offset inadequate payments for complementary services. The Committee shares this view, and believes the legislation achieves this goal.

Section 304. Demonstration Project for Use of Recovery Audit Contractors.

Current Law

No provision.

Explanation of Provision

The Secretary would be required to conduct a demonstration project for up to three years on the use of recovery audit contractors under the Medicare Integrity Program. The recovery audit contractors would identify underpayments and overpayments in the Medicare program and would recoup overpayments made to providers. Payment would be made to these contractors by

providing incentives for good performance. The Secretary would be able to waive Medicare statutory provisions to pay for the services of the recovery audit contractors. The Secretary would be required to examine the efficacy of using these contractors with respect to duplicative payments, accuracy of coding, and other payment policies in which inaccurate payments arise. The demonstration project would be required to cover at least two states among the states with the highest per-capita utilization rates of Medicare services and have at least three contractors.

Recovery of an overpayment through this project would not prohibit the Secretary or the Attorney General from investigating and prosecuting appropriate allegations of fraud and abuse. Fiscal intermediaries, carriers, and Medicare Administrative Contractors would not be eligible to participate as a recovery audit contractor. The Secretary would be required to show preference to contracting with entities that have demonstrated more than three years direct management experience and a proficiency in recovery audits. Within six months of completion, the Secretary would be required to report to Congress on the project's savings to the Medicare program, including recommendations on the cost-effectiveness of extending or expanding the program.

Effective Date

Upon enactment.

Reason for Change

This is a common approach used in the private sector including physicians and hospitals to recover payments from insurers. It provides a useful check on whether the other CMS contractors are paying accurately and identifying potential fraud problems.

D. TITLE IV - RURAL HEALTH CARE IMPROVEMENTS

Section 401. Enhanced Disproportionate Share Hospital (DSH) Treatment for Rural Hospitals and Urban Hospitals with Fewer than 100 Beds.

Current Law

Medicare makes additional payments to certain acute hospitals that serve a large number of low-income Medicare and Medicaid patients as part of its inpatient prospective payment system (PPS). As specified by BIPA, starting with discharges occurring on or after April 1, 2001, all hospitals are eligible to receive Medicare disproportionate share hospital (DSH) payments when their DSH percentage or threshold amount exceeds fifteen.

Different formulas are used to establish a hospital's DSH payment, depending upon the hospital's location, number of beds and status as a rural referral center (RRC) or sole community hospital (SCH). The DSH adjustment that a small urban or rural hospital can receive is limited to 5.25 percent of total Medicare inpatient payments.

Explanation of Provision

For discharges after October 1, 2003, a small rural or urban hospital that qualifies for a DSH adjustment would potentially receive an increase in DSH payments. The DSH adjustment for these hospitals, except for rural referral centers, would be almost doubled but not to exceed a maximum of 10 percent.

Effective Date

The provision would apply to discharges occurring on or after October 1, 2003.

Reason for Change

MedPAC, an independent advisory committee that advises Congress, recommended this policy in its March 2003 report. MedPAC believes this change would mitigate the effects of uncompensated care for many rural hospitals and thereby protect Medicare beneficiaries' access to care in rural communities. Historically, rural and small urban hospitals have been treated unfairly with respect to DSH payments.

Section 402. Immediate Establishment of Uniform Standardized Amount in Rural and Small Urban Areas.

Current Law

Medicare pays for inpatient services in acute hospitals in large urban areas using a standardized amount that is 1.6 percent larger than the standardized amount used to reimburse hospitals in other areas (both rural areas and smaller urban areas). The Consolidated Appropriations Act of 2003 (P.L. 108-7) provided for a temporary payment increase to rural and small urban hospitals; all Medicare discharges from April 1, 2003, to September 30, 2003, would be paid on the basis of the large urban area amount.

Explanation of Provision

Beginning for discharges in FY2004, the standardized amount for hospitals located in areas other than large urban areas would be equal to the amount used to pay hospitals located in large urban areas. Technical conforming amendments would also be adopted.

Effective Date

Upon enactment.

Reason for Change

MedPAC recommends eliminating this differential in payment. MedPAC found no statistically significant difference in costs between the cost of hospitals in large urban areas (over one million) and other hospitals, after removing the effect of geographic differences in wages, teaching and other Medicare adjustments.

Section 403. Establishment of Essential Rural Hospital Classification.

Current Law

No provision in current law.

Explanation of Provision

An Essential Rural Hospital would be a new designation for the purposes of Medicare reimbursement. To be eligible for the Essential Rural Hospital designation, the hospital must have more than 25 beds and must be located in a rural area. The Secretary must then determine that the closure of the hospital would significantly diminish the ability of beneficiaries to obtain essential health care services based on certain criteria. Specifically, the Secretary must determine that (1) a high proportion of Medicare beneficiaries residing in the hospital's service area receive basic inpatient care from the hospital, and (2) there exists, in the service area, a hospital with more than 200 licensed beds that provides specialized surgical care to a high percentage of beneficiaries. Regardless of the size of the hospital, almost all physicians in the area must have admitting privileges and provide their inpatient services primarily at the hospital. Also, the Secretary must determine that the closure of the hospital would have a significant adverse impact on the availability of health care service in the absence of the hospital.

In making such determination, the Secretary may also consider: (1) whether ambulatory care providers in the hospital's service area are insufficient to handle the outpatient care of the hospital, (2) whether beneficiaries would have difficulty accessing care, and (3) whether the hospital has a commitment to provide graduate medical education in a rural area. The essential rural hospital would have to have a quality of care score above the median state scores.

A hospital classified as an essential rural hospital would not be able to change such classification. An essential rural hospital would not be able to be treated as a sole community hospital, Medicare dependent hospital, or rural referral center. A hospital that is classified as an essential rural hospital for a cost reporting period beginning on or after October 1, 2004 would be reimbursed 102 percent of its reasonable Medicare costs for inpatient and outpatient services. Beneficiary cost-sharing amounts would not be affected and required billing for such services would not be waived.

Effective Date

The provision would apply to cost reporting periods beginning on or after October 1, 2004.

Reason for change

The purpose of this provision is to recognize the impact of certain hospitals whose existence is essential in the health care delivery system of the community. Some rural hospitals have high fixed costs because of the necessity for providing the capacity for essential services in a community. There are also problems with the definition and payment for some communities

and rural referral hospitals. This would provide a new crosscutting designation field for hospitals that can meet the criteria.

Section 404. More Frequent Update in Weights Used in Hospital Market Basket.

Current Law

Medicare's standardized amounts, which serve as the basis for its payment per discharge from acute hospitals, are increased annually using an update factor which is determined in part by the projected increase in the hospital market basket. The market basket is a fixed-weight hospital input price index, which measures the average change in the price of goods and services hospitals purchased in order to furnish inpatient care. CMS revises the cost category weights, reevaluate the price proxies for such categories, and rebase (or changes the base period) for the market basket every five years. CMS implemented a revised and rebased market basket using 1997 cost data for use in the FY2003 Medicare hospital payment rates.

Explanation of Provision

The Secretary would be required to revise the market basket cost weights including the labor share to reflect the most currently available data and to establish a schedule for revising the cost weights more often than once every five years. The Secretary would be required to submit a report to Congress by October 1, 2004 on the reasons for and the options considered in establishing such a schedule.

Effective Date

Upon enactment.

Reason for Change

At the current time the hospital market basket is only updated every ten years using five-year-old data for the weights including the labor share. Statisticians at the Department of Labor and other experts believe the measures of inflation should be updated on a more regular basis to correct consistent inaccuracies over time.

Section 405. Improvements to the Critical Access Hospital (CAH) Program.

(a) Increase in Payment Amounts.

Current Law

Generally, a critical access hospital (CAH) receives reasonable, cost-based reimbursement for care rendered to Medicare beneficiaries. CAHs may elect either a cost-based hospital outpatient service payment or an all-inclusive rate, which is equal to a reasonable cost payment for facility services plus 115 percent of the fee schedule payment for professional

services. Ambulance services that are owned and operated by CAHs are reimbursed on a reasonable cost basis if these ambulance services are 35 miles from another ambulance system.

Explanation of Provision

Inpatient, outpatient, and covered skilled nursing facility services provided by a CAH would be reimbursed at 102 percent of reasonable costs of services furnished to Medicare beneficiaries.

Effective Date

This provision would apply to cost reporting periods beginning on or after October 1, 2003.

Reason for change

Small hospitals need the ability to build up reserves and to finance new capital expenditures. This provides a margin for these hospitals under the Medicare program, often their most important payor.

(b) Coverage of Costs For Certain Emergency Room On-Call Providers.

Current Law

BIPA required the Secretary to include the costs of compensation (and related costs) of on-call emergency room physicians who are not present on the premises of a CAH, are not otherwise furnishing services, and are not on-call at any other provider or facility when determining the allowable, reasonable cost of outpatient CAH services.

Explanation of Provision

Reimbursement of on-call emergency room providers would be expanded to include the costs associated with physician assistants, nurse practitioners, and clinical nurse specialists as well as emergency room physicians for covered Medicare services.

Effective Date

This provision would apply to costs for services provided on or after January 1, 2004.

Reason for Change

In sparsely populated areas, it is often the physician assistant or nurse practitioner employed by a physician practice or operating independently who is providing the on call services for the emergency room. This recognizes the bonuses that hospitals pay for their services.

(c) Modification of the Isolation Test for Cost-Based CAH Ambulance Services.

Current Law

Ambulance services provided by a CAH or provided by an entity that is owned or operated by a CAH is paid on a reasonable cost basis and not the ambulance fee schedule, if the CAH or entity is the only provider or supplier of ambulance services that is located within a 35-mile drive of the CAH.

Explanation of Provision

The 35-mile requirement would not apply to the ambulance services that are furnished by a provider or supplier of ambulance services who is determined by the Secretary to be a first responder to emergencies.

Effective Date

This provision would apply to ambulance services furnished on or after the first cost reporting period that begins after the date of enactment.

Reason for Change

CAHs may not be eligible for cost-based reimbursement because other ambulances may come into the area to transport patients between hospitals or to transfer patients to/from nursing homes. This would ensure that CAHs owned-and-operated ambulances would be paid cost when they are the first responders to an emergency.

(d) Reinstatement of Periodic Interim Payment (PIP).

Current Law

Eligible hospitals, skilled nursing facilities, and hospices, which meet certain requirements, receive Medicare periodic interim payments (PIP) every two weeks; these payments are based on estimated annual costs without regard to the submission of individual claims. At the end of the year, a settlement is made to account for any difference between the estimated PIP payment and the actual amount owed. A CAH is not eligible for PIP payments.

Explanation of Provision

An eligible CAH would be able to receive payments made on a PIP basis for its inpatient services. The Secretary would be required to develop alternative methods based on the expenditures of the hospital for these PIP payments.

Effective Date

This provision would apply to payments made on or after January 1, 2004.

Reason for Change

Small rural hospitals often have significant changes in volume due to the season or just on a day-to-day basis. This provision averages payments over time to aid the hospital's financial stability.

(e) Condition for Application of Special Physician Payment Adjustment.

Current Law

As specified by BBRA, CAHs can elect to be paid for outpatient services using cost-based reimbursement for its facility fee and at 115 percent of the fee schedule for professional services otherwise included within its outpatient critical access hospital services for cost reporting periods starting on or after October 1, 2000.

Explanation of Provision

The Secretary would not be able to require that all physicians providing services in a CAH assign their billing rights to the entity in order for the CAH to be able to be paid on the basis of 115 percent of the fee schedule for the professional services provided by the physicians. However, a CAH would not receive payment based on 115 percent of the fee schedule for any individual physician who did not assign billing rights to the CAH.

Effective Date

This provision would be effective as if it had been included as part of BBRA.

Reason for Change

This provision ensures that the intent of Congress is for CMS to provide these payments in order to attract physicians to CAHs.

(f) Flexibility in Bed Limitation for Hospitals.

Current Law

A CAH is a limited service facility that must provide 24-hour emergency services and operate a limited number of inpatient beds in which hospital stays can average no more than 96 hours. A CAH cannot operate more than 15 acute-care beds at one time, but can have an additional 10 swing beds that are set up for skilled nursing facility (SNF) level care. SNF beds in a unit of the facility that is licensed as a distinct-part skilled nursing facility at the time of the facility's application for CAH designation are not counted toward these bed limits.

Explanation of Provision

The Secretary would be required to specify standards for determining whether a CAH has seasonal variations in patient admissions that would justify a 5-bed increase in the number of beds it can maintain (and still retain its classification as a CAH). CAHs that operate swing beds would be able to use up to 25 beds for acute care services as long as no more than 10 beds at any time are used for non-acute services. Those CAHs with swing beds that made this election would not be eligible for the 5-bed seasonal adjustment. A CAH with swing beds that elects to operate only 15 of its 25 beds as acute care beds would be eligible for the 5-bed seasonal adjustment.

Effective Date

These provisions would only apply to CAH designations made before, on or after January 1, 2004.

Reason for Change

These provisions allow some needed flexibility in the CAH program designation to ensure that if there is a flu epidemic or major accident that the hospital would have the capacity to treat those patients.

(g) Additional 5-Year Period of Funding for Grant Program.

Current Law

The Secretary is able to make grants for specified purposes to States or eligible small rural hospitals that apply for such awards. The authorization to award the grants expired in FY2002.

Explanation of Provision

The authorization to award grants would be established from FY2004 through FY2008 from the Federal Hospital Insurance Trust Fund at amounts of up $25 million each year.

Effective Date

Upon enactment.

Reason for change

This would continue the planning and monitoring aspects of the states for the CAH program. The Committee expects that the states would work in cooperation with the critical access hospitals in determining the best use of the funds.

Section 406. Redistribution of Unused Resident Positions.

Current Law

Medicare has different resident limits for counting residents, its indirect medical education (IME) adjustment and for reimbursement for a teaching hospital's direct graduate medical education (DGME) costs. Generally, a hospital's IME adjustment depends on a hospital's teaching intensity as measured by the ratio of the number of interns and residents per bed. Prior to BBA 97, the number of residents that could be counted for IME purposes included only those in the hospital inpatient and outpatient departments. Effective October 1, 1997, under certain circumstances a hospital may now count residents in non-hospital sites for the purposes of IME. Medicare's DGME payment to teaching hospital is based on its updated cost per resident (subject to a locality adjustment and certain payment corridors), the weighted number of approved full-time-equivalent (FTE) residents, and Medicare's share of inpatient days in the hospital. Generally, the resident counts of both IME and DGME payments are based on the number of residents in approved allopathic and osteopathic teaching programs that were reported by the hospital for the cost reporting period ending in calendar year 1996. The DGME resident limit is based on the unweighted resident counts. Hospitals that established new training programs before August 5, 1997 are partially exempt from the cap. Other exceptions apply to certain hospitals including those with new programs established after that date. Hospitals in rural areas (and non-rural hospitals operating training programs in rural areas) can be reimbursed for 130 percent of the number of residents allowed by their cap. Under certain conditions, an affiliated group of hospitals under a specific arrangement may combine their resident limits into an aggregate limit. Subject to these resident limits, a teaching hospital's IME and DGME payments are based on a three-year rolling average of resident counts, that is, the resident count will be based on the average of the resident count in the current year and the two preceding years. The rolling average calculation includes podiatry and dental residents.

Explanation of Provision

A teaching hospital's total number of potentially Medicare-reimbursed resident positions would be reduced for cost reporting periods, starting January 1, 2004, if the resident reference level is less than its applicable resident limit. If so, the reduction would equal to 75 percent of the difference between the hospital's limit and its resident reference level. The resident reference level would be the highest number of allopathic and osteopathic resident positions (before the application of any weighting factors) for the hospital during the reference period. A hospital's reference period would be the 3 most recent consecutive cost reporting periods for which a hospital's cost reports have been settled (or in the absence of such settled cost reports, submitted reports) on or before September 30, 2002. The Secretary would be able to adjust a hospital's resident reference level, upon the timely request for such an adjustment, for the cost reporting period that includes July 1, 2003.

The Secretary would be authorized to increase the applicable resident limits for other hospitals by an aggregate number that does not exceed the overall reduction in such limits. No increase would be permitted for any portion of cost reporting period that occurs before July 1,

2003 or before the date of a hospital's application for such an increase. No increase would be permitted unless the hospital has applied for such an increase by December 1, 2005.

The Secretary would consider the need for an increase in the physician specialty and the location involved. The Secretary would first distribute the increased resident count to programs in hospitals located in rural areas and hospitals that are not in large urban areas on a first-come-first-serve basis. The hospital would have to demonstrate that the resident positions would be filled; not more than 25 positions would be given to any one hospital. These hospitals would be reimbursed for DGME for the increase in resident positions at the locality adjusted national average per resident amount. Changes in a hospital's resident count established under this section would increase a hospital's IME payments. These provisions would not apply to reductions in residency programs that occurred as part of the voluntary reduction program or would affect the ability of certain hospitals to establish a new medical residency training programs. The Secretary would be required to submit a report, including recommendations, on whether to extend the application deadline for increases in resident limits no later than July 1, 2005.

Effective Date

Upon enactment.

Reason for Change

An unintended effect of the resident cap was to lock in a maldistribution of DGME and IME resident training positions in the country. Due to the strong link between the location of a resident's training and their eventual practice, it is critical to get more residents into training programs in rural areas and small urban cities. This provision redistributes unused residency slots, over a five-year period, to hospitals that have either reached their cap or have been providing DGME residencies without Medicare funding.

Section 407. Two-Year Extension of Hold Harmless Provisions for Small Rural Hospitals and Sole Community Hospitals Under Prospective Payment System for Hospital Outpatient Department Services.

Current Law

The PPS for hospital outpatient departments (HOPDs) was implemented in August 2000 for most acute care hospitals. Under the HOPD PPS, Medicare pays for covered services using a fee schedule based on ambulatory payment classifications (APCs). Rural hospitals with no more than 100 beds are paid no less under this PPS system than they would have received under the prior reimbursement system for covered HOPD services because of hold harmless provisions. The hold harmless provisions apply to services provided before January 1, 2004.

Explanation of Provision

The hold harmless provisions governing HOPD reimbursement for small rural hospitals would be extended to January 1, 2006. The hold harmless provisions would be extended to sole community hospitals located in a rural area starting for services furnished on or after January 1, 2004 until January 1, 2006. The Secretary would be required to conduct a study to determine if the costs by APC groups incurred by rural providers exceed such costs incurred by urban providers. If appropriate, the Secretary would provide a payment adjustment to reflect the higher costs of rural providers by January 1, 2005.

Effective Date

Upon enactment.

Reason for Change

During the proposed rule for the start of the HOPD PPS, CMS found that rural hospital costs were higher than other hospitals. CMS did not recommend adjusting payments due to the poor quality of the data. This continues the hold harmless from any negative effect from the PPS for small rural hospitals and extends it to sole community hospitals until the Secretary reexamines this issue.

Section 408. Exclusion of Certain Rural Health Clinic and Federally Qualified Health Center Services from the Prospective Payment System for Skilled Nursing Facilities.

Current Law

Under the PPS, skilled nursing facilities (SNFs) are paid a predetermined amount to cover all services provided in a day, including the costs associated with room and board, nursing, therapy, and drugs; the daily payment would vary depending upon a patient's therapy, nursing and special care needs as established by one of 44 resource utilization groups (RUGs). Certain services and items provided a SNF resident, such as physicians' services, specified ambulance services, chemotherapy items and services, and certain outpatient services from a Medicare-participating hospital or critical access hospital, are excluded from the SNF PPS and paid separately under Part B.

Explanation of Provision

Services provided by a rural health clinic (RHCs) and a federally qualified health center (FQHC) after January 1, 2004 would be excluded from SNF PPS, if such services were excluded if furnished by an physician or practitioner who was not affiliated with a RHC or FQHC.

Effective Date

The provision would apply to services furnished on or after January 1, 2004.

Reason for Change

In some rural areas, local physicians may be employed in a rural health clinic or federally qualified health clinic. This would allow them to get paid for their professional services to skilled nursing patients like other physicians.

Section 409. Recognition of Attending Nurse Practitioners as Attending Physicians to Serve Hospice Patients.

Current Law

Medicare covers hospice services to care for the terminal illnesses of the beneficiary. In general, beneficiaries who elect the hospice benefit give up other Medicare services that seek to treat the terminal illness or that duplicate services provided by the hospice. Services are provided primarily in the patient's home by a Medicare-approved hospice. Reasonable and necessary medical and support services for the management of the terminal illness are furnished under a written plan-of-care established and periodically reviewed by the patient's attending physician and the hospice. To be eligible for Medicare's hospice care, a beneficiary must be certified as terminally ill by an attending physician and the medical director or other physician at the hospice and elect hospice treatment. An attending physician who may be an employee of the hospice is identified by the patient as having the most significant role in the determination and delivery of his or her medical care when the patient makes an election to receive hospice care.

Explanation of Provision

A beneficiary would be able to identify a nurse practitioner (who is not employed by the hospice) as an attending physician. The nurse practitioner would not be able to certify the beneficiary as terminally ill.

Effective Date

Upon enactment.

Reason for change

In rural areas, the independent nurse practitioner provides a significant amount of the care to patients up to and during their terminal illness. This allows them to continue in their clinical role with the patient.

Section 410. Improvement in Payments to Retain Emergency Capacity for Ambulance Services in Rural Areas.

Current Law

Traditionally, Medicare has paid suppliers of ambulance services on a reasonable charge basis and paid provider-based ambulances on a reasonable cost basis. BBA 97 provided for the establishment of a national fee schedule, which was to be implemented in phases. The required fee schedule became effective April 1, 2002 with full implementation by January 2006. In the transition period, a gradually decreasing portion of the payment is to be based on the prior payment methodology (either reasonable costs or reasonable charges which were subject to national limitation amounts).

The fee schedule payment amount equals the base rate for the level of service plus payment for mileage and specified adjustment factors. Additional mileage payments are made in rural areas. BIPA increased payment for rural ambulance mileage for distances greater than 17 miles and up to 50 miles for services provided before January 1, 2004. The amount of the increase was at least one-half of the payment per mile established in the fee schedule for the first 17 miles of transport.

Explanation of Provision

The Secretary would be required to increase the base rate of the fee schedule for ground ambulance services that originate in a qualified rural area to account for the higher average costs incurred by providers furnishing a low volume of services. A qualified rural area is a county that has not been assigned to a metropolitan statistical area (MSA) with a population density of Medicare beneficiaries in the lowest quartile of all rural county populations.

Effective Date

Upon enactment.

Reason for Change

The current adjustment may overpay rural ambulances in more populated areas and underpays them in less populated areas. Recent analyses by the General Accounting Office suggest that it is fixed costs – represented by the base rate – not mileage that are the significant factor for increased costs in rural areas. In particular, the ambulances in the lowest 25 percent of rural counties may have less than one trip per day.

Section 411. Two-Year Increase for Home Health Services Furnished in a Rural Area.

Current Law

The Medicare home health PPS, implemented on October 1, 2000, provides a standardized payment for a 60-day episode of care furnished to a Medicare beneficiary. Medicare's payment is adjusted to reflect the type and intensity of care furnished and area wages as measured by the hospital wage index. BIPA increased PPS payments by 10 percent for home health services furnished in the home of beneficiaries living in rural areas during the two-year period beginning April 1, 2001, through March 31, 2003, without regard to certain budget-neutrality provisions applying to home health PPS. The temporary additional payment is not included in the base for determination of payment updates.

Explanation of Provision

The provision would extend a five percent additional payment for home health care services furnished in a rural area during FY 2004 and 2005 without regard to certain budget-neutrality requirements.

Effective Date

Upon enactment.

Reason for Change

MedPAC recommends extending the five percent add-on for one-year while further analysis is done on rural agency home health margins. The two-year extension is to provide Congress with time to evaluate that information and decide what action is needed, if any.

Section 412. Providing Safe Harbor for Certain Collaborative Efforts that Benefit Medically Underserved Populations.

Current Law

People who knowingly and willfully offer or pay a kickback, a bribe, or rebate to directly or indirectly induce referrals or the provision of services under a Federal program may be subject to financial penalties and imprisonment. Certain exceptions or safe harbors that are not considered violations of the anti-kickback statute have been established.

Explanation of Provision

Remuneration in the form of a contract, lease, grant, loan or other agreement between a public or non-profit private health center and an individual or entity providing goods or services to the health center would not be a violation of the anti-kickback statute if such an agreement would contribute to the ability of the health center to maintain or increase the availability or

quality of services provided to a medically underserved population. The Secretary would be required to establish standards, on an expedited basis, related to this safe harbor that would consider whether the arrangement: (1) results in savings of Federal grant funds or increased revenues to the health center, (2) expands or limits a patient's freedom of choice, and (3) protects a health care professional's independence regarding the provision of medically appropriate treatment. The Secretary would also be able to include other standards that are consistent with Congressional intent in enacting this exception. The Secretary would be required to publish an interim final rule in the Federal Register no later than 180 days from enactment that would establish these standards. The rule would be effective immediately, subject to change after a public comment period of not more than 60 days.

Effective Date

Upon enactment

Reason for Change

This would finalize policy under development at the Department of Health and Human Services.

Section 413. GAO Study of Geographic Differences.

Current Law

No provision.

Explanation of Provision

GAO would be required to study geographic differences in payment amounts in the physician fee schedule including: (1) an assessment of the validity of each component of the geographic adjustment factors; (2) an evaluation of the measures and the frequency with which they are revised; and (3) an evaluation of the methods used to establish the costs of professional liability insurance including the variation between physician specialties and among different states, the update to the geographic cost of practice index, and the relative weights for the malpractice component. The study, including recommendations concerning use of more current data and use of cost data rather than price proxies, would be due to Congress within 1 year of enactment.

Effective Date

Upon enactment.

Section 414. Treatment of Missing Cost Reporting Periods for Sole Community Hospitals.

Current Law

Sole community hospitals (SCHs) are hospitals that, because of factors such as isolated location, weather conditions, travel conditions, or absence of other hospitals, are the sole source of inpatient services reasonably available in a geographic area, or are located more than 35 road miles from another hospital. The primary advantage of an SCH classification is that these hospitals receive Medicare payments based on the current national PPS national standardize amount or on hospital-specific per discharge costs from either FY 1982, FY1987 or FY1996 updated to the current year, whatever amount would provide the highest Medicare reimbursement. The FY1996 base year option became effective for discharges on or after FY2001 on a phased in basis and would be fully implemented for SCH discharges on or after FY2004.

Explanation of Provision

A hospital would not be able to be denied treatment as a SCH or receive payment as a SCH because data are unavailable for any cost reporting period due to changes in ownership, changes in fiscal intermediaries, or other extraordinary circumstances, so long as data from at least one applicable base cost reporting period is available.

Effective Date

The provision would apply to cost reporting periods beginning on or after January 1, 2004.

Reason for Change

During changes in fiscal intermediaries or in a change of ownership, historical information on a provider can be lost or misplaced. The purpose of the sole community hospital program is to provide for additional payment to protect access, which should not be stymied due to human error. Since sole community hospitals are paid the higher of any of the base years or the Federal rate, this does not result in preferential payments for these hospitals compared to other sole community hospitals.

Section 415. Extension of Telemedicine Demonstration Project.

Current Law

BBA 97 authorized a telemedicine demonstration project for beneficiaries with diabetes mellitus in medically underserved rural or inner-city areas. BBRA required the Secretary to award the demonstration to the best technical proposal as of the bill's enactment date, no later

than three months after enactment without additional review. BBRA also clarified that qualified medically underserved rural or urban inner-city areas are federally designated medically underserved areas or Health Provider Shortage Areas (HPSAs) at the time of enrollment in the project. Furthermore, it made changes in the project's data requirements, and limited beneficiary cost-sharing. The demonstration would expire in February 2004.

Explanation of Provision

This provision would extend the demonstration for an additional four years.

Effective Date

Upon enactment.

Reason for Change

Difficulty finding appropriate participants delayed the demonstration's start. This extension would provide additional time to fully evaluate the clinical effectiveness of the program, and to determine the long-term effectiveness of the approach. It would also provide more time to collect clinical data to evaluate the project's cost-effectiveness.

Section 416. Adjustment to the Medicare Inpatient Hospital PPS Wage Index to Revise the Labor-Related Share of Such Index.

Current law

Hospitals' DRG payments are adjusted by the hospital wage index. The adjusted portion of the payment is determined by the labor share. The labor share has three components: wages (50.7 percent), fringe benefits (11 percent), and rest is the so-called labor related costs.

Explanation of Provision

It reduces the labor share down to 62 percent of wages and fringe benefits for those areas with wage index values under 1.0. All other areas are held harmless from the change in the labor share.

Effective Date

October 1, 2003.

Reason for Change

MedPAC and others have questioned whether some or all of the labor related costs in the labor share should be included. This eliminates these costs from the labor share for the areas that benefit from such a change.

Section 417. Medicare Incentive Payment Program Improvements for Physician Scarcity.

Current Law

Under the Medicare Incentive Program, physicians receive a 10 percent bonus payment for services provided in health professional shortage areas. Physicians are responsible for indicating their eligibility for this bonus on their billing forms.

Explanation of Provision

This provision would establish a new five percent bonus payment program for physicians providing care to Medicare beneficiaries in physician scarcity areas. The Secretary would calculate two measures of scarcity. A primary care scarcity area would be determined based on the number of primary care physicians per Medicare beneficiary -- the primary care ratio. A specialty care scarcity area would be based on the number of specialty care physicians per Medicare beneficiary -- the specialty care ratio. The number of physicians would be based on physicians who actively practice medicine or osteopathy, and would exclude physicians whose practice is exclusively for the Federal Government, physicians who are retired, or physicians who only provide administrative services.

The Secretary would rank each county or area based on its primary care ratio. Primary care scarcity counties or areas would be those counties or areas with the lowest primary care ratios, such that 20 percent of Medicare beneficiaries reside in these counties, when each county or area is weighted by the number of Medicare beneficiaries in the county or area. Specialty care scarcity counties or areas would be identified in the same manner, using the specialty care ratio. There would be no administrative or judicial review of the identification of counties or areas, or of a specialty of any physician.

To the extent feasible, the Secretary would treat a rural census tract of a metropolitan statistical area, as determined under the most recent modification of the Goldsmith Modification, as an equivalent area for purposes of qualifying as a primary care scarcity area or specialty care scarcity area.

The Secretary would be required to publish a list of all areas which would qualify as primary care scarcity counties or specialty care scarcity counties as part of the proposed and final rules to implement the physician fee schedule.

The provision would also include improvement to the Medicare Incentive Payment Program, which provides a 10 percent bonus to physicians in shortage areas. The Secretary would be required to establish procedures under which the Secretary, and not the physician furnishing the service, would be responsible for determining when a bonus payment should be made. As part of the physician proposed and final rule for the physician fee schedule, the Secretary would be required to include a list of all areas which would qualify as a health professional shortage area for the upcoming year.

Effective Date

Upon enactment.

Reason for Change

The new five percent bonus for physicians in either primary care scarcity counties or specialty care scarcity counties would increase financial incentives for physicians to provide care to Medicare beneficiaries in these areas with a shortage of physicians. This bonus payment would make it easier to recruit and retain physicians in these scarcity areas.

Improvements to the Medicare Incentive Program would shift responsibility for identifying eligibility for the 10 percent bonus from physicians to the Secretary.

E. TITLE V - PROVISIONS RELATING TO PART A

Subtitle A - Inpatient Hospital Services

Section 501. Revision of Acute Hospital Payment Updates.

Current Law

Each year, Medicare's operating payments to hospitals are increased or updated by a factor that is determined in part by the projected annual change in the hospital market basket. Congress establishes the update for Medicare's inpatient PPS for operating costs, often several years in advance.

Explanation of Provision

Acute hospitals would receive a market basket update minus 0.4 percent for three years. This results in an average 3.1 percent update for FY2004 through FY2006, equivalent to market basket minus 0.4 percent. The Secretary is also directed to compile and clarify the procedures and policies for billing for blood and blood costs in the hospital outpatient setting as well as the operation of the collection of the blood deductible.

Effective Date

Upon enactment

Reason for Change

MedPAC unanimously recommended that Congress increase payments by 3.1 percent instead of the scheduled 3.5 percent. This results in a $3 billion increase in hospital payments for FY 2004. This is 0.4 percent less than current law due to expected increases in productivity.

According to MedPAC, the modest expected productivity increase for hospitals is lower than would be considered to be sufficient for many private industries.

There is little precedent for hospitals to receive a full market basket increase. Congress has only given hospitals the full inflationary increase twice since the start of the hospital prospective payment system. Congress has legislated multiple-year changes in every Medicare bill except in the Omnibus Budget Reconciliation Act of 1989. Finally, this is a comparatively generous provision since Congress has typically reduced the inflationary offset by 1.2 percent—three times greater than the 0.4 percent recommended by MedPAC and presented in the bill.

The proposal replaces a historical saw tooth pattern of updates ranging from zero to full market basket to put hospitals' Medicare payments on a predictable stable funding path.

Section 502. Recognition of New Medical Technologies Under Inpatient Hospital PPS.

Current Law

BIPA established that Medicare's inpatient hospital payment system should include a mechanism to recognize the costs of new medical services and technologies for discharges beginning on or after October 1, 2001. The additional hospital payments can be made by means of new technology groups, an add-on payment, a payment adjustment, or other mechanism, but cannot be a separate fee schedule and must be budget-neutral. A medical service or technology will be considered to be new if it meets criteria established by the Secretary after notice and the opportunity for public comment. CMS published the final regulation implementing these provisions on September 7, 2001. This regulation changed the meeting schedule for decisions on the creation and implementation of new billing codes (ICD-9-CM codes). The regulation also established that technology providing a substantial improvement to existing treatments would qualify for additional payments. The add-on payment for eligible new technology would occur when the standard diagnosis-related group (DRG) payment was inadequate; this threshold was established as one standard deviation above the mean standardized DRG. In these cases, the add-on payment for new technology would be the lesser of (a) 50 percent of the costs of the new technology, or (b) 50 percent of the amount by which the costs exceeded the standard DRG payment; however, if the new technology payments are estimated to exceed the budgeted target amount of one percent of the total operating inpatient payments, the add-on payments are reduced prospectively.

Medicare pays hospitals additional amounts for atypical cases that have extraordinarily high costs compared to most discharges classified in the same DRG. The additional payment amount is equal to 80 percent of the difference between the hospital's entire cost for the stay and the threshold amount.

Explanation of Provision

The Secretary would be required to add new diagnosis and procedure codes in April 1 of each year that would not be required to affect Medicare's payment or DRG classification until the fiscal year that begins after that date. The Secretary would not be able to deny a service or technology treatment as a new technology because the service (or technology) has been in use prior to the 2-to-3 year period before it was issued a billing code and a sample of specific discharges where the service has been used can be identified. When establishing whether DRG payments are inadequate, the Secretary would be required to apply a threshold that is 75 percent of one standard deviation for the DRG involved.

The Secretary would be required to provide additional clarification in regulating the criteria used to determine whether a new service represents an advance in technology that substantially improves the existing diagnosis or treatment. The Secretary would be required to deem that a technology provides a substantial improvement on an existing treatment if the technology in question: (1) is a drug or a biological that is designated under section 506 of the Federal Food, Drug, and Cosmetic Act, approved under section 314.510 or 601.41 of Title 21, Code of Federal Regulations, designated for priority review when the marketing application was filed, or (2) is a medical device for which an exemption has been granted under section 520(m) of such Act, or for which priority or expedited review has been provided under section 515(d)(5). For other technologies that may be substantial improvements, the Secretary would be required to: (1) maintain and update a public list of pending applications for specific services and technologies to be evaluated for eligibility for additional payment; (2) accept comments, recommendations, and data from the public regarding whether a service or technology represents a substantial improvement; and (3) provide for a meeting at which organizations representing physicians, beneficiaries, manufacturers or other interested parties may present comments, recommendations, and data to the clinical staff of CMS regarding whether a service or technology represents a substantial improvement. These actions would occur prior to the publication of the proposed regulation.

Before establishing an add-on payment as the appropriate reimbursement mechanism, the Secretary would be directed to identify one or more DRGs and assign the technology to that DRG, taking into account similar clinical or anatomical characteristics and the relative cost of the technology. The Secretary would assign an eligible technology into a DRG where the average cost of care most closely approximates the cost of the new technology. In such a case, no add-on payment would be made; the application of the budget-neutrality requirement with respect to annual DRG reclassifications and recalculation of associated DRG weights would not be affected. The Secretary would be required to increase the percentage associated with add-on payments from 50 percent to the marginal rate or the percentage that Medicare reimburses inpatient outlier cases.

The Secretary would be directed to automatically reconsider an application as a new technology that was denied for FY2003 as a FY2004 application under these new provisions. If such an application were granted, the maximum time period otherwise permitted for such classification as a new technology would be extended by 12 months.

Effective Date

These provisions would be effective for classifications beginning in FY2004.

Reason for Change

CMS has only approved one new technology since these provisions were passed. This provision would allow more technologies to be covered and recognizes that the breakthrough technologies are new costs to the system.

Section 503. Increase in Federal Rate for Hospitals in Puerto Rico.

Current Law

Under Medicare's prospective payment system for inpatient services, a separate standardized amount is used to establish payments for discharges from short-term general hospitals in Puerto Rico. BBA 97 provides for an adjustment of the Puerto Rico rate from a blended amount based on 25 percent of the federal national amount and 75 percent of the local amount to a blended amount based on a 50/50 split between national and local amounts.

Explanation of Provision

Hospitals in Puerto Rico would receive Medicare payments based on a 50/50 split between federal and local amounts before October 1, 2003. From FY2004 - FY2007, an increasing amount of the payment rate would be based on federal national rates as follows: during FY2004, payment would be 59 percent national and 41 percent local; this would change to 67 percent national and 33 percent local during FY2005 and 75 percent national and 25 percent local during FY2006 and subsequent years.

Effective Date

Upon enactment.

Reason for Change

Puerto Ricans pay the full Hospital Insurance payroll tax but they are not afforded equal Medicare payments to their hospitals. This partially redresses the inequality between the rates, and is consistent with the MedPAC recommendation.

Section 504. Wage Index Adjustment Reclassification Reform.

Current Law

Acute hospitals may apply to the Medicare Geographic Classification Review Board (MGCRB) for a change in classification from a rural area to an urban area, or reassignment from one urban area to another urban area, based on the level of wages. The MGCRB was created to determine whether a hospital should be redesignated to an area of close proximity for purposes of using that area's standardized amount, wage index, or both. If the MGCRB grants reclassification, the new wage index would be used to calculate Medicare's payment for inpatient and outpatient services. Generally, hospitals must demonstrate a close proximity to the areas where they seek to be reclassified. A hospital can meet this criteria if one of two conditions are met: (1) an urban hospital is no more than 15 miles and a rural hospital is no more than 35 miles from the area where it wants to be reclassified, or (2) at least 50 percent of the hospital's employees are residents of the area. A rural referral center (RRC) or a sole community hospital (SCH) or a hospital that is both a RRC and a SCH does not have to meet the proximity criteria. After establishing appropriate proximity, a hospital may qualify for the payment rate of another area if it proves that its incurred costs are comparable to those of hospitals in that area under established criteria. To use an area's wage index, a rural hospital must demonstrate that its average hourly wage is equal to at least 82 percent of the average hourly wage of hospitals in the area to which it seeks redesignation; an urban hospital must demonstrate that its average hourly wage is at least 84 percent of such an area. In addition, an urban hospital cannot be reclassified unless its average hourly wage is at least 108 percent of the average hourly wage of the area in which it is located. This standard is 106 percent for rural hospitals seeking reclassification to another area.

For redesignations starting in FY2003, the average hourly wage comparisons used to determine whether a hospital can use another area's wage index are based on 3 years worth of lagged data submitted by hospitals as part of their cost report. For instance, FY2003 wage index reclassifications were based on weighted three-year averages of average hourly wages using data from FY1997, FY1998, and FY1999 cost reports. Wage index reclassifications are effective for 3 years unless the hospital notifies the MCGRB and withdraws or terminates its reclassification.

Explanation of Provision

The Secretary would be required to establish an application process and payment adjustment to recognize the commuting patterns of hospital employees. A hospital that qualified for such a payment adjustment would have average hourly wages that exceed the average wages of the area in which it is located and have at least ten percent of its employees living in one or more areas that have higher wage index values. This qualifying hospital would have its wage index value increased by the average difference in wage index values between the higher areas and its own, weighted by the percentage of its employees who live in these areas. The process would be based on the MGCRB reclassification process and schedule with respect to data submitted. Such an adjustment would be effective for three years unless a hospital withdraws or terminates its payment. A hospital that receives a commuting wage adjustment would not be

eligible for reclassification into another area by the MCGRB for the purposes of using its wage index or standardized amount. These commuting wage adjustments would not affect the computation of the wage index of the area in which the hospital is located or any other area. It would also be exempt from certain budget neutrality requirements.

Enactment Date

Upon enactment.

Reason for change

Labor market areas may differ from the distance requirements in the regulations on reclassification. Thus, using commuting patterns of employees more clearly reflects the underlying labor market that hospitals confront. This policy will have the effect of blurring the current hard line of payment adjustments between two adjacent MSAs.

Section 505. MedPAC Report on Specialty Hospitals.

Current Law

No provision.

Explanation of Provision

MedPAC would be required to conduct a study of specialty hospitals compared with other similar general acute hospitals including the number and extent of patients referred by physicians with an investment interest in the facility, the quality of care furnished, the impact of the specialty hospital on the acute general hospital, and the differences in the scope of services, Medicaid utilization and the amount of uncompensated care that is furnished. The report, including recommendations, would be due to Congress no later than 1 year from enactment.

Enactment Date

Upon enactment.

Subtitle B - Other Services

Section 511. Payment for Covered Skilled Nursing Facility Services.

Current Law

Medicare uses a system of daily rates to pay for care in a skilled nursing facility (SNF). There are 44 daily rate categories, known as resource utilization groups (RUGs), and each group reflects a different case mix and intensity of services, such as skilled nursing care and/or various therapies and other services.

Explanation of Provision

The per diem RUG payment for a SNF resident with acquired immune deficiency syndrome (AIDS) would be increased by 128 percent. This payment increase would not apply after the date when the Secretary certifies that the SNF case mix adjustment adequately compensates for the facility's increased costs associated with caring for a resident with AIDS.

Enactment Date

The provision would be effective for services on or after October 1, 2003.

Reason for Change

According to prior work by the Urban Institute, AIDS patients have much higher costs than other patients in the same resource utilization groups in skilled nursing facilities. The adjustment is based on that data analysis.

Section 512. Coverage of Hospice Consultation Services.

Current Law

Current law authorized coverage of hospice services, in lieu of certain other Medicare benefits, for terminally ill beneficiaries who elect such coverage.

Explanation of Provision

Coverage of certain physicians' services for certain terminally ill individuals would be authorized. Persons entitled to these services would be individuals who have not elected the hospice benefit and have not previously received these physicians' services. Covered services would be those furnished by a physician who is the medical director or employee of a hospice program. Services would include evaluating the individual's need for pain and symptom management, counseling the individual with respect to end-of-life issues and care options, and advising the individual regarding advanced care planning. Payment for such services would equal the amount established for similar services under the physician fee schedule, excluding the practice expense component.

Effective Date:

The provision would apply to consultation services provided by a hospice program on or after January 1, 2004.

Reason for Change

Many patients, especially those with congestive heart failure, are not educated about the option of receiving hospice services to alleviate their pain and suffering. Moreover, hospice lengths of stay keep dropping, suggesting that patients are referred too late in their illness. This provision would encourage physicians to talk more with patients about hospice.

F. TITLE VI - PROVISIONS RELATING TO PART B

Subtitle A – Physicians' Services

Section 601. Revision of Updates for Physicians' Services.

Current Law

Medicare pays for services of physicians and certain non-physician practitioners on the basis of a fee schedule. The fee schedule, in place since 1992, is intended to relate payments for a given service to the actual resources used in providing that service. The fee schedule assigns relative values to services. These relative values reflect physician work (i.e., the time, skill, and intensity it takes to provide the service), practice expenses, and malpractice costs. The relative values are adjusted for geographic variations in costs. The adjusted relative values are then converted into a dollar payment amount by a conversion factor.

The law provides a specific formula for calculating the annual update to the conversion factor. The intent of the formula is to place a restraint on overall increases in spending for physicians' services. Several factors enter into the calculation of the formula. These include: (1) the sustainable growth rate (SGR), which is essentially a target for Medicare spending growth for physicians' services, (2) the Medicare economic index (MEI), which measures inflation in the inputs needed to produce physicians' services, and (3) an adjustment that modifies the update, which would otherwise be allowed by the MEI, to bring spending in line with the SGR target. The SGR target is not a limit on expenditures. Rather, the fee schedule update reflects the success or failure in meeting the target. If expenditures exceed the target, the update for a future year is reduced.

The annual percentage update to the conversion factor equals the MEI, subject to an adjustment (known as the update adjustment factor) to match target spending for physicians' services under the SGR system. (During a transition period, 2001-2005, an additional adjustment is made to achieve budget neutrality.) The update adjustment sets the conversion factor at a level so that projected spending for the year would meet allowed spending by the end of the year. Allowed spending for the year is calculated using the SGR. However, in no case can the update adjustment factor be less than minus seven percent or more than plus three percent.

The update adjustment factor is the sum of: (1) the prior year adjustment component, and (2) the cumulative adjustment component. The prior year adjustment component is determined

by: (1) computing the difference between allowed expenditures for physicians' services for the prior year and the amount of actual expenditures for that year, (2) dividing this amount by the actual expenditures for that year, and (3) multiplying that amount by 0.75. The cumulative adjustment component is determined by: (1) computing the difference between allowed expenditures for physicians' services from April 1, 1996 through the end of the prior year and the amount of actual expenditures during such period, (2) dividing that difference by actual expenditures for the prior year as increased by the SGR for the year for which the update adjustment factor is to be determined, and (3) multiplying that amount by 0.33.

The law also specifies a formula for calculating the SGR that is based on changes in four factors: (1) the estimated change in fees, (2) the estimated change in average number of Part B enrollees (excluding Medicare+Choice beneficiaries), (3) the estimated projected growth in real gross domestic product (GDP) per capita, and (4) the estimated change in expenditure due to changes in law or regulations. This formula is designed to adjust for how well actual expenditures meet SGR target expenditures.

Provisions in the Consolidated Appropriations Resolution of 2003 (P.L. 108-7) permitted redeterminations of SGR for prior years to correct for faulty data for the number of FFS beneficiaries in 1998 and 1999. As a result, the conversion factor for 2003 was increased 1.6 percent over the 2002 level. Other aspects of the formula for the annual payment rate were not addressed.

CMS estimates an update of -4.2 percent for 2004, followed by a smaller negative update in 2005.

Explanation of Provision

The update to the conversion factor for 2004 and 2005 would be not less than 1.5 percent**.**

The formula for calculating the sustainable growth rate would be modified. Starting in 2003, the GDP factor would be based on the annual average change over the preceding 10 years (a 10-year rolling average.) The current GDP factor measures the 1-year change from the preceding year.

Effective Date

Upon enactment. The 10-year rolling average calculation of the GDP would apply to computations of the SGR starting in 2003.

Reason for Change

CMS actuaries project a –4.2 percent update for 2004 and a smaller negative update for 2005. This provision would prevent those negative updates from occurring, and provide for modest increases in physician payment rates. These modest increases would ensure continuing access to physician services for Medicare beneficiaries.

The provision also includes a 10-year rolling average calculation of GDP as a modest change to the update formula. This change would promote stability in the physician updates over time by limiting the volatility of the SGR payments, which now oscillate dramatically based on year-to-year changes in economic performance.

Section 602. Studies on Access to Physicians Services.

Current Law

Periodic analyses by the Physician Payment Review Commission, MedPAC, and CMS showed that access to physicians' services remained generally adequate for most beneficiaries through 1999. Detailed data is not available for a subsequent period; however, several recent surveys show a decline in the percentage of physicians accepting new Medicare patients.

Explanation of Provision

GAO would be required to conduct a study on access of Medicare beneficiaries to physicians' services under Medicare. The study would include an assessment of beneficiaries' use of services through an analysis of claims data. It would also examine changes in use of physicians' services over time. Further, it would examine the extent to which physicians are not accepting new Medicare beneficiaries as patients. GAO would be required to submit a report to Congress on this study within 18 months of enactment. The report would include a determination whether data from claims submitted by physicians indicate potential access problems for beneficiaries in certain geographic areas. The report would also include a determination whether access by beneficiaries to physicians' services has improved, remained constant, or deteriorated over time.

The Secretary would be required to request the Institute of Medicine to conduct a study on the adequacy of the supply of physicians (including specialists) in the country and the factors that affect supply. The Secretary would be required to submit the results of the study in a report to Congress no later than 2 years of the date of enactment.

Effective Date

Upon enactment.

Section 603. MedPAC Report on Payment for Physicians' Services.

Current Law

Medicare pays for physicians' services on the basis of a fee schedule. The fee schedule assigns relative values to services. These relative values reflect physician work, practice expenses and malpractice expenses. Resource-based practice expense relative values were phased-in beginning in 1999. Beginning in 2002, the values were totally resource-based.

Certain services have a professional component and a technical component. The technical component does not include a relative value for physician work. A global value includes both the professional and technical components. The physician must bill for the global value if the physician furnishes both the professional component and the technical component.

Explanation of Provision

MedPAC would be required to report to Congress on the effects of refinements to the practice expense component in the case of services for which there are no physician work relative value units. The report is to examine the following by specialty: (1) the effects of refinements on payments for physicians services, (2) interaction of the practice expense component with other components of and adjustments to payment for physicians' services, (3) appropriateness of the amount of compensation by reason of such refinements, (4) effect of such refinements on access to care by Medicare beneficiaries to physicians' services, and (5) effect of such refinements on physician participation under the Medicare program. The report would be due within one year of enactment.

Effective Date

Upon enactment.

Subtitle B - Preventive Services

Section 611. Coverage of an Initial Preventive Physical Examination.

Current Law

Medicare covers a number of preventive services. However, it does not cover routine physical examinations.

Explanation of Provision

Medicare would cover an initial free preventive physical examination. The physical examination would be defined as physicians' services consisting of a physical examination with the goal of health promotion and disease detection. It would include items and services (excluding clinical laboratory tests) consistent with the recommendations of the United States Preventive Services Task Force as determined by the Secretary. A covered initial preventive physical examination would be one performed no later than six months after the individual's initial coverage date under Part B. Initial preventive physical exams would be included in the definition of physicians' services for purposes of the physician fee schedule. The Part B deductible and coinsurance would be waived for initial preventive physical exams.

Effective Date

The provision would apply to services furnished on or after January 1, 2004 for those individuals whose coverage begins on or after such date.

Reason for Change

The US Preventive Services Task Force has recommended coverage of a preventive physical exam. An initial physical exam for new Medicare beneficiaries would permit identification of any health problems and allow for initiation of appropriate treatment, thereby reducing more acute and expensive interactions with the health care system in the future.

Section 612. Coverage of Cholesterol and Blood Lipid Screening.

Current Law

Medicare covers a number of preventive services. However, it does not cover cholesterol and blood lipid screening.

Explanation of Provision

Medicare coverage of cholesterol and blood lipid screening would be authorized. The screening would be defined as diagnostic testing of cholesterol and other lipid levels of the blood for the purpose of early detection of abnormal cholesterol and other lipid levels. The Secretary would be required to establish standards regarding the frequency and type of these screening tests, but not more often than once every two years.

Effective Date

The provision would apply to services furnished on or after January 1, 2005.

Reason for Change

The US Preventive Services Task Force has recommended coverage of cholesterol and blood lipid screening for the elderly. This preventive care benefit would allow for early detection and treatment of health problems.

Section 613. Waiver of Deductible for Colorectal Cancer Screening Tests.

Current Law

Covered colorectal screening tests for prevention purposes include: (1) an annual fecal-occult blood test for individuals age 50 and older, (2) flexible sigmoidoscopy every four years for individuals age 50 and older, (3) colonoscopy for high-risk individuals every two years and for other individuals every 10 years, and (4) screening barium enemas every four years for individuals age 50 and older who are not at high risk of developing colorectal cancer or every two years for high risk individuals. Payment is made according to the applicable payment system for the provider performing the test.

Colorectal cancer screening tests are subject to beneficiary cost sharing amounts, including an annual deductible and coinsurance amount.

Explanation of Provision

The Part B deductibles would be waived for colorectal cancer screening tests.

Effective Date

The provision would apply to items and services furnished on or after January 1, 2004.

Reason for Change

Beneficiaries have not availed themselves of preventive colorectal cancer screening tests to the extent anticipated after Medicare coverage of these tests became available under BBA 97. This provision would waive the deductible to increase beneficiary use of these important screening tests.

Section 614. Improved Payment for Certain Mammography Services.

Current Law

Screening mammography coverage includes the radiological procedure as well as the physician's interpretation of the results of the procedure. The usual Part B deductible is waived for tests. Payment is made under the physician fee schedule.

Certain services paid under fee schedules or other payment systems including ambulance services, services for patients with end-stage renal disease paid under the ESRD composite rate, professional services of physicians and non-physician practitioners paid under the physician fee schedule, and laboratory services paid under the clinical diagnostic laboratory fee schedule are excluded from Medicare's HOPD PPS.

Explanation of Provision

Unilateral and bilateral diagnostic mammography as well as screening mammography services would be excluded from the HOPD PPS. The Secretary would be required to provide an appropriate adjustment to the physician fee schedule for the technical component of the diagnostic mammography based on the most recent cost data available. This adjustment would be applied to services provided on or after January 1, 2004.

Effective Date

The provision would apply to mammography performed on or after January 1, 2004.

Reason for Change

Mammography services are paid at a much lower rate under the HOPD PPS than in the physician office. This establishes a level playing field across sites of service, thereby increasing beneficiary access to important preventive services.

Subtitle C - Other Services

Section 621. Hospital Outpatient Department (HOPD) Payment Reform.

(a) Payment for Drugs.

Current Law

Under the HOPD PPS, the unit of payment is the individual service or procedure as assigned to one of about 570 ambulatory payment classifications (APCs) groups. Services are classified into APCs based on their Health care Common Procedure Coding System (HCPCS), a standardized coding system used to identify products, supplies, and services for claims processing and payment purposes. To the extent possible, integral services and items including drugs are bundled or packaged within each APC. For instance, an APC for a surgical procedure would include operating and recovery room services, anesthesia and surgical supplies. Medicare's payment for HOPD services is calculated by multiplying the relative weight associated with an APC by a geographically adjusted conversion factor. The conversion factor is updated on a calendar year schedule and the annual updates are based on the hospital market basket (MB). Currently, the CY 2004 HOPD update would equal the projected change in the MB.

Medicare pays for covered outpatient drugs in one of three ways: (1) as a transitional pass-through, (2) as a separate APC, or (3) packaged into an APC with other services.

Transitional pass-through payments are supplemental payments to cover the incremental cost associated with certain medical devices, drugs and biologicals that are inputs to an existing service. The additional payment for a given item is established for two or three years and then the costs are incorporated into the APC relative weights. BBRA specified that pass-through payments would be made for current orphan drugs, as designated under section 526 of the Federal Food, Drug, and Cosmetic Act; current cancer therapy drugs, biologicals, and brachytherapy; current radiophamaceutical drugs and biological products; and new drugs and biological agents.

Generally, CMS has established that a pass-through payment for an eligible drug is based on the difference between 95 percent of its average wholesale price and the portion of the otherwise applicable APC payment rate attributable to the existing drug, subject to a budget neutrality provision. The pass-through amount for new drugs with a substitute drug recognized in a separate drug APC payment is the difference between 95 percent of new drug AWP and the payment rate for the comparable dose of the associated drug APC.

Hospital costs for these drugs are used to establish the beneficiary copayment amounts as well as to project the amount of pass-through spending to calculate the uniform reduction to

payments under the budget neutrality constraint. These hospital costs are imputed by multiplying the drug's AWP by the applicable cost to charge ratio, which varies by the class of drug. Although transitional pass-through payments are subject to a budget neutrality requirement, the applicable budget neutrality requirement (2.5 percent through CY2003) was not effective until April 2002.

Current drugs and biologicals that have been in transitional pass-through status on or prior to January 1, 2000, were removed from that payment status effective January 1, 2003. CMS established separate APC payments for certain drugs, including orphan drugs, blood and blood products, and selected higher cost drugs in CY2003. CMS established a threshold of $150 for a drug to qualify for a separate APC payment as a higher-cost drug. Other drugs that had qualified for a transitional pass-through payment were packaged in to procedural APCs. For example, in some instances, brachytherapy seeds (radioactive isotopes used in cancer treatments) were packaged into payments for brachytherapy procedures. Essentially, the payment rates for these drug-related APCs are based on a relative weight calculated in the same way as procedural APCs are calculated.

Temporary HCPCS codes are used exclusively to bill pass-through payments for new technology items paid under the HOPD PPS. These codes cannot be used to bill other Medicare payment systems. These codes are added, changed or deleted on a quarterly basis to expedite the processing of requests for pass-through status.

Explanation of Provision

Starting for services furnished on or after January 1, 2004, certain covered HOPD drugs would be paid no more than 95 percent of AWP or less than the transition percentage of the AWP from CY2004 through CY2006. In subsequent years, payment would be equal to average price for the drug in the area and year established by the competitive acquisition program under 1847A. The covered HOPD drugs affected by this provision are radiopharmaceuticals and outpatient drugs that were paid on a pass-through basis on or before December 31, 2002. These would not include drugs for which pass-through payments are first made on or after January 1, 2003, or those drugs for which a temporary HCPCS code has not been assigned. Drugs for which a temporary HCPCS code has not been assigned would be reimbursed at 95 percent of AWP.

The transition percentage to AWP for sole-source drugs manufactured by one entity is 83 percent in CY2004, 77 percent in CY2005, and 71 percent in CY2006. The transition percentage to AWP for innovator multiple source drugs is 81.5 percent in CY2004, 75 percent in CY2005, and 68 percent in CY2006. The transition percentage to AWP for multiple source drugs with generic drug competitors is no more than 46 percent in CY2004 through CY2006. Generally, a multiple source drug is a covered drug for which there are two or more therapeutically equivalent drug products. An innovator multiple source drug is a multiple source drug that was originally marketed under an original new drug application approved by the Food and Drug Administration (FDA). A sole source drug is not a multiple source drug. The additional expenditures resulting from these provisions would not be subject to the budget neutrality requirement.

Starting in CY2004, the Secretary would be required to lower the threshold for establishing a separate APC group for higher cost drugs from $150 to $50. These separate drug APC groups would not be eligible for outlier payments because their payment already increases when the dose increases.

Starting in CY2004, Medicare's transitional pass-through payments for drugs and biologicals covered under a competitive acquisition contract would reflect the amount paid under that contract, not 95 percent of AWP.

Reason for Change

A GAO study found significant problems with the reimbursement for drugs and biologicals under the hospital outpatient system. Some drugs were reimbursed a small amount of AWP while others were paid far in excess of AWP. Hospital charges were not designed to specifically capture the resource costs for specific items. Some hospitals charge a flat markup on all drugs; some hospitals charge a lower markup on low cost drugs compared to high cost drugs while others do the opposite. As a result, the APC drug prices ranged from paying 0.2 percent of AWP to 29,000 percent of 95 percent AWP, and paid the median generic drugs more than sole source drugs. This provision establishes a glide path to the hospital acquisition cost numbers from the Kathpol survey undertaken by CMS. Thereafter, a level playing field with drug prices across sites of service would be established. CMS is asked to collect data from hospitals on their acquisition to be used to adjust the rates if necessary.

(b) Special Payment for Brachytherapy.

Current Law

Current drugs and biologicals that have been in transitional pass-through status on or prior to January 1, 2000 were removed from that payment status effective January 1, 2003. CMS established separate APC payments for certain drugs, including orphan drugs, blood and blood products, and selected higher cost drugs in CY2003. CMS established a threshold of $150 per claim for a drug to qualify for a separate APC payment as a higher-cost drug. Other drugs that had qualified for a transitional pass-through payment were packaged into procedural APCs. For example, in some instances, brachytherapy seeds (radioactive isotopes used in cancer treatments) were packaged into payments for brachytherapy procedures. Essentially, the payment rates for these drug-related APCs are based on a relative weight calculated in the same way as procedural APCs are calculated.

Explanation of Provision

From January 1, 2004 through December 31, 2006, Medicare's payments for brachytherapy devices would equal the hospital's charges adjusted to costs. The Secretary would be required to create separate APCs to pay for these devices that reflect to the number, isotope, and radioactive intensity of such devices. This would include separate groups for palladium-103 and iodine-125 devices. GAO would be required to study the appropriateness of payments for

brachytherapy devices and submit a report including recommendations to Congress no later than January 1, 2005.

Effective Date

Upon enactment.

Reason for Change

The amount of seeds necessary to treat the patient can vary significantly. This changes the payment methodology to reflect differences in clinical resources.

(c) Functional Equivalence.

Current Law

In the November 1, 2002, *Federal Register* final rule, CMS decided that a new anemia treatment for cancer patients was no longer eligible for pass-though payments because it was functionally equivalent (although not structurally identical or therapeutically equivalent) to an existing treatment. The transitional pass-through rate for the drug was reduced to zero starting for services in 2003.

Explanation of Provision

The Secretary would be prohibited from applying a functional equivalence standard or any similar standard that deems a particular drug or biological to be similar or identical to another drug (and therefore ineligible for pass-through payment status) without first developing these standards by regulation. Such regulation would be required to: (1) be published after a public comment period, (2) contain criteria that provides for coordination with the Food and Drug Administration, and (3) be based on scientific studies that demonstrate the clinical relationship between the drugs in question. This provision would apply to the application of a functional equivalent determination on or after the date of enactment. The provision prohibits the application of this standard to a drug or biological prior to June 13, 2003.

Effective Date

Upon enactment.

Reason for Change

The concept of functional equivalence is new to the Medicare program and should be open to comment by Congress and the public through proposed rulemaking. The FDA should be involved since these are scientific issues for which CMS lacks expertise.

(d) Hospital Acquisition Cost Study.

Current Law

CMS estimates hospital costs to establish beneficiary copayment amounts as well as to project the amount of pass-through spending to calculate the uniform reduction to payments under the budget neutrality constraint. These hospital costs are imputed by multiplying AWP for the drug by the applicable cost to charge ratio, which varies by the class of drug.

Explanation of Provision

The Secretary would be required to study the hospital acquisition costs related to covered outpatient drugs that cost $50 and more that are reimbursed under the HOPD PPS. The study would encompass a representative sample of urban and rural hospitals. The report should include recommendations on the usefulness of the cost data and frequency of subsequent data collection and would be due to Congress no later than January 1, 2006. The report should also discuss whether the data is appropriate for making adjustments to payments made under the competitive acquisition contract established by section 1847A and whether separate estimates should be made for overhead costs (i.e. handling and administering drugs).

Effective Date

Upon enactment.

Section 622. Payment for Ambulance Services.

Current Law

Traditionally, Medicare has paid suppliers of ambulance services on a reasonable charge basis and paid provider-based ambulances on a reasonable cost basis. BBA 97 provided for the establishment of a national fee schedule, which was to implemented in phases, in an efficient and fair manner. The required fee schedule became effective April 1, 2002, with full implementation by January 2006. In the transition period, a gradually decreasing portion of the payment is to be based on the prior payment methodology (either reasonable costs or reasonable charges).

The fee schedule payment amount equals the base rate for the level of service plus payment for mileage and specified adjustment factors. Additional mileage payments are made in rural areas. BIPA increased payment for rural ambulance mileage for distances greater than 17 miles and up to 50 miles for services provided before January 1, 2004. The amount of the increase was at least one-half of the payment per mile established in the fee schedule for the first 17 miles of transport.

Explanation of Provision

The phase-in methodology and schedule for full implementation of the ambulance fee schedule would be modified. The calculation of ambulance fees in the phase-in period would

incorporate a decreasing portion of the payment based on regional fee schedules calculated for each of nine census regions for those regions that lose financially under the fee schedule. Generally, the regional fee schedules would be based on the same methodology and data used to construct the national fee schedule. For services provided in 2004, the blended rate would be based on 20 percent of the national fee schedule and 80 percent of the regional fee schedule; in 2005 blended rate would be based on a 40 percent national and 60 percent regional split; in 2006, the blended rate would be based on a 60 percent national and 40 percent regional split; from 2007-2009, the blended rate would be based on an 80 percent national and 20 percent regional split; and in 2010 and subsequently, the ambulance fee schedule would be based on the national fee schedule.

Medicare's payments for ground ambulance services would be increased by one quarter of the amount otherwise established for trips longer than 50 miles occurring on or after January 1, 2004 and before January 1 2009. The payment increase would apply regardless of where the transportation originated. GAO would be required to submit an initial report to Congress on the access and supply of ambulance services in regions and states where ambulance payments are reduced by December 31, 2005. GAO would be required to submit a final report to Congress by January 1, 2004.

Effective Date

The provision would apply to ambulance services furnished on or after January 1, 2004.

Reason for Change

New PPS systems cannot capture all the reasons for past regional differences in cost. This proposal is modeled on the transition of the hospital inpatient PPS and acts to slow down the losses in regions that lose significantly under the new fee schedule.

Section 623. Renal Dialysis Services.

(a) Demonstration of Alternative Delivery Models.

Current Law

The Secretary announced a demonstration project establishing a disease-management program that would allow organizations experienced with treating end-stage renal disease (ESRD) patients to develop financing and delivery approaches to better meet the needs of beneficiaries with ESRD. CMS is soliciting a variety of types of organizations to coordinate care to patients with ESRD, encourage the provision of disease-management services for these patients, collect clinical performance data and provide incentives for more effective care.

Explanation of Provision

The provision would require the Secretary to establish an advisory board for the ESRD disease management demonstration. The advisory board would be comprised of representatives

of patient organizations, clinicians, MedPAC, the National Kidney Foundation, the National Institute of Diabetes and Digestive and Kidney Diseases of the National Institutes of Health, ESRD networks, Medicare contractors to monitor quality of care, providers of services and renal dialysis facilities furnishing end-stage renal disease services, economists, and researchers.

Effective Date

Upon enactment.

Reason for change

This provision would allow more patient oversight of the demonstration of changes to the payments system for such a frail population.

(b) Restoring Composite Rate Exceptions for Pediatric Facilities.

Current Law

Prior to BIPA, an increase in the composite rate would trigger an opportunity for facilities to request an exception to the composite rate in order to receive higher payments. BIPA prohibited the Secretary from granting new exceptions to the composite rate from applications received after July 1, 2001.

Explanation of Provision

The prohibition on exceptions would not apply to pediatric ESRD facilities as of October 1, 2002. Pediatric facilities would be defined as a renal facility with 50 percent of its patients under 18 years old.

Effective Date

Upon enactment.

Reason for Change

Pediatric patients require more nursing oversight and more time to receive dialysis treatment. This would recognize the higher costs of facilities that treat these patients.

(c) Increase in Renal Dialysis Composite Rate for Services Furnished in 2004.

Current Law

Dialysis facilities providing care to beneficiaries with end-stage renal disease (ESRD) receive a fixed prospectively determined payment amount (the composite rate) for each dialysis treatment. BBRA increased the composite rates by 1.2 percent for dialysis services furnished in both 2000 and 2001. BIPA subsequently increased the mandated 2001 update to 2.4 percent, an

increase that was to implemented on the following schedule in order to avoid a disruption in claims processing: for services furnished from January through March, 2001, the 1.2 percent increase specified by BBRA applied; for the remainder of 2001, a transition increase of 2.79 percent applied. Effective January 1, 2002, the composite rates reflected the 2.4 percent increase. There is no rate increase scheduled for ESRD composite payment rate in 2004.

Explanation of Provision

The provision would increase the ESRD composite payment rate by 1.6 percent for 2004.

Effective Date

Upon enactment.

Reason for Change

The Medicare Payment Advisory Commission recommended this increase in the composite rate for 2004.

Section 624. One-Year Moratorium on Therapy Caps; Provisions Relating to Reports.

Current Law

BBA 97 established annual payment limits per beneficiary for all outpatient therapy services provided by non-hospital providers. The limits applied to services provided by independent therapists as well as to those provided by comprehensive outpatient rehabilitation facilities (CORFs) and other rehabilitation agencies. There are two beneficiary limits. The first is a $1,500 per beneficiary annual cap for all outpatient physical therapy services and speech language pathology services. The second is a $1,500 per beneficiary annual cap for all outpatient occupational therapy services. Beginning in 2002, the amount increases by the Medicare Economic Index (MEI), rounded to the nearest multiple of $10. The limits do not apply to outpatient services provided by hospitals. BBRA 99 percent suspended application of the therapy limits in 2000 and 2001. BIPA extended the suspension through 2002. Although the therapy caps were scheduled for implementation in January 2003, they are not yet being enforced. CMS has scheduled implementation for July 2003.

Therapy patients must be under the care of a physician. The physician or therapist must develop a treatment plan, and the physician must review the plan periodically.

BBA 97 required the Secretary to report to Congress by January 1, 2001, on recommendations for a revised coverage policy of outpatient physical therapy and occupational therapy services based on a classification of individuals by diagnostic category and prior use of services, in both inpatient and outpatient settings, in place of uniform dollar limitations. BIPA required the Secretary to conduct a study on the implications of eliminating Medicare's in-room supervision requirement for physical therapy assistants supervised by physical therapists its

implication on the physical therapy cap. A report on the study was due within 18 months of enactment.

Explanation of Provision

Application of the therapy caps would be suspended during CY 2004. The Secretary would be required to submit the reports required by BBA 97 and BIPA by December 31, 2003. The Secretary would be required to request the Institute of Medicine to identify conditions or diseases that should justify conducting an assessment of the need to waive the therapy caps. The Secretary would be required to submit to Congress a preliminary report on the conditions and diseases identified by July 1, 2004. A final report, including recommendations, would be due by October 1, 2004.

GAO would be required to conduct a study on access to physical therapist services in states authorizing access to such services without a physician referral compared to states that require such a physician referral. The study would: (1) examine the use of and referral patterns for physical therapist services for patients age 50 and older in states that authorize such services without a physician referral and in states that require such a referral, (2) examine the use of and referral patterns for physical therapist services for patients who are Medicare beneficiaries, (3) examine the physical therapist services within the facilities of the Department of Defense, and (4) analyze the potential impact on beneficiaries and on Medicare expenditures of eliminating the need for a physician referral for physical therapist services under the Medicare program. GAO would be required to submit a report to Congress on the study within one year of enactment.

Effective Date

Upon enactment.

Reason for Change

The Secretary has not provided a recommendation to Congress of criteria, with respect to conditions and diseases, under which a waiver of therapy caps would apply for individual Medicare beneficiaries. The implementation of therapy caps would be waived for 2004 because the Secretary has failed to provide a recommendation. The Secretary would have until October 1, 2004 to provide a recommendation to Congress.

Section 625. Adjustment to Payments for Services Furnished in Ambulatory Surgical Centers.

Current Law

Medicare uses a fee schedule to pay for the facility services related to a surgery provided in an ACS. The associated physician services (surgery and anesthesia) are reimbursed under the physician fee schedule. CMS maintains the list of approved ASC procedures that is required to be updated every 2 years. The Secretary is required to update ASC rates based on a survey of the

actual audited costs incurred by a representative sample of ASCs every 5 years beginning no later than January 1, 1995. Between revisions, the rates are to be updated annually on a calendar year schedule using the CPI-U. From FY1998 through FY2002, the update was established as the CPI-U minus 2.0 percentage points, but not less than zero.

Explanation of Provision

The update would be reduced two percentage points for five years. ASCs would get an increase calculated as the CPI-U minus 2.0 percentage points (but not less than zero) in each of the fiscal years from 2004 through 2008.

Effective Date

Upon enactment.

Reason for Change

MedPAC made three recommendations regarding ASCs, including a freeze on payments for 2004. This update would allow ASCs a small increase in payments while a more permanent solution is developed. The Committee urges CMS and ASCs to complete the collection of recent ASC charge and cost data, so that the ASC payment system can be analyzed and revised. Furthermore, the Committee recognizes the inconsistency in payments to ASCs and HOPD PPS rates for the same procedures. ASCs are urged to cooperate with CMS in providing recent charge and cost data to prevent changes to ASC payments that might not be supported if full data were available.

Section 626. Payment for Certain Shoes and Inserts under the Fee Schedule for Orthotics and Prosthetics.

Current Law

Subject to specified limits and under certain circumstances, Medicare would pay for extra-depth shoes with inserts or custom molded shoes with inserts for an individual with severe diabetic foot disease. Coverage is limited to one of the following within a calendar year: (1) one pair of custom-molded shoes (including inserts provided with such shoes) and two additional pairs of inserts, or (2) one pair of extra-depth shoes (not including inserts provided with such shoes) and three pairs of inserts. An individual may substitute modifications of custom-molded or extra-depth shoes instead of obtaining one pair of inserts, other than the initial pair of inserts. Footwear must be fitted and furnished by a podiatrist or other qualified individual such as a pedorthist, orthotist, or prosthetist. The certifying physician may not furnish the therapeutic shoe unless the physician is the only qualified individual in the area.

Payment is made on a reasonable charge basis, subject to upper limits established by the Secretary. These limits are based on 1988 amounts that were set forth in Section 1833(o) of the Act and then adjusted by the same percentage increases allowed for DME fees except that if the updated limit is not a multiple of $1, it is rounded to the nearest multiple of $1. The Secretary or

a carrier may establish lower payment limits than established by statute if shoes and inserts of an appropriate quality are readily available at lower amounts.

Although updates in payment for diabetic shoes is related to that used to increase the DME fee schedule, the shoes are not subject to DME coverage rules or the DME fee schedule. In addition, diabetic shoes are neither considered DME nor orthotics, but a separate category of coverage under Medicare Part B.

Explanation of Provision

Payment for diabetic shoes would be limited by the amount that would be paid if they were considered to be a prosthetic or orthotic device. The Secretary or a carrier would be able to establish lower payment limits than these amounts if shoes and inserts of an appropriate quality are readily available at lower amounts. The Secretary would be required to establish a payment amount for an individual substituting modifications to the covered shoe that would assure that there is no net increase in Medicare expenditures.

Effective Date

The provision would apply to items furnished on or after January 1, 2004.

Reason for Change

The payment for shoes was determined based on an arbitrary amount set in the statute. The amount exceeded the retail price for some comparable items. This treats diabetic shoes the same as all other durable medical equipment.

Section 627. Waiver of Part B Late Enrollment Penalty for Certain Military Retirees; Special Enrollment Period.

Current Law

A late enrollment penalty is imposed on beneficiaries who do not enroll in Medicare Part B upon becoming eligible for Medicare.

Explanation of Provision

Congress enacted TRICARE for Life, which re-established TRICARE health care coverage as a wraparound to Medicare for military retirees, age 65 and older. To take advantage of the TRICARE for Life program, military retirees must be enrolled in Medicare Part B. There is a late enrollment penalty for military retirees who do not enroll in Medicare Part B upon becoming eligible for Medicare. This provision would waive the late enrollment penalty for military retirees, 65 and older, who enroll(ed) in the TRICARE for Life program from 2001–2004.

The Secretary would also be required to provide a special enrollment period for these military retirees beginning as soon as possible after enactment and ending December 31, 2004. For the individual who enrolls during the special enrollment period, coverage would begin on the first day of the month, following the month in which the individual enrolled.

Effective Date

The provision would apply to premiums for months beginning with January 2004. A method would be established to provide rebates of premium penalties paid for by military retirees for months on or after January 2004.

Reason for Change

The Floyd A. Spence National Defense Authorization Act for FY 2001 opened TRICARE to Medicare-eligible military retirees for the first time, allowing them to keep their military health benefits past the age of 65. This benefit became available for the first time on January 1, 2001.

This provision would eliminate two barriers prevent many retirees from accessing these benefits. First, many retirees who received military care in military health facilities on a space-available basis did not purchase Part B coverage when initially eligible. Upon late enrollment, they must pay a 10 percent penalty for each year that enrollment was delayed. Second, because Medicare enrollment is only available during an annual open enrollment season, from January 1 to March 31 each year, many retirees would have to wait until 2004 to secure coverage.

The waiver of the late-enrollment penalty and provision for a special enrollment period would remove these barriers.

Section 628. Part B Deductible.

Current Law

Under Part B, Medicare generally pays 80 percent of the approved amount for covered services after the beneficiary pays an annual deductible of $100. The Part B deductible has set at $100 since 1991.

Explanation of Provision

The Medicare Part B deductible would rise from $100 in 2003 to $104 in 2004, and grow with Medicare inflation thereafter. As a result, the Part B deductible would grow at the same rate as expenditures per capita for Part B services. The amount would be rounded to the nearest dollar.

Effective Date

Upon enactment.

Reason for Change

In 1966, Medicare's $50 Part B deductible equaled about 45 percent of Part B charges. Today's $100 deductible equals about three percent of such charges. Indexing the Part B deductible to grow at the same rate as total Part B spending per beneficiary would maintain the deductible at 3 percent of such charges over time.

An unchanged Part B deductible is a benefit increase over time, as costs of medical care rise. Beneficiaries pay about 25 percent of this benefit increase, through increased Part B premiums; taxpayers finance the remaining 75 percent. The Part B deductible has increased only three times since the beginning of Medicare, when it was $50. The deductible has since been increased to $60 in 1973, $75 in 1982, and $100 in 1991. About one-half of beneficiaries are insulated from Part B deductibles through Medigap, Medicaid, or employer-sponsored supplemental insurance that covers the Part B deductible.

Section 629. Extension of Coverage of Intravenous Immune Globulin (IVIG) for the Treatment of Primary Immune Deficiency Diseases in the Home.

Current Law

Currently, Medicare provides reimbursement under Part B for the infusion of IVIG in a hospital outpatient or physician office setting.

Explanation of Change

The proposal would permit patients with primary immune deficiency to receive IVIG at home instead of in the currently covered settings. Unlike the other settings, however, home coverage would include only the cost of the drug; patients would be responsible for the cost of a nurse or other health care professional to administer the infusion.

Effective Date

Applies to items furnished on or after January 1, 2004.

Reason For Change

Primary immune deficiency diseases are inherited disorders in which parts of the body's immune system are missing or do not function properly. These disorders affect more than 50,000 Americans. In order to maintain their health, most primary immune deficiency patients require monthly infusions of a plasma derivative known as intravenous immune globulin (IVIG). Without this life saving therapy, primary immune deficient patients would be subject to serious infection, illness and premature death.

Given their compromised immune systems, these patients are particularly vulnerable to the many infections to which individuals in a hospital or other health care facility are exposed.

Home coverage of these infusions for appropriate patients would reduce this health risk and be significantly more convenient.

The Balanced Budget Refinement Act directed the Department of Health and Human Services to study the feasibility of allowing the existing covered drug to be reimbursed when delivered in the home. The study, conducted by the Lewin Group, examined issues such as cost, safety, access to care, and the practices of private insurers. The study concluded home coverage of IVIG is appropriate.

G. TITLE VII – PROVISIONS RELATING TO PARTS A AND B

Subtitle A – Home Health Services

Section 701. Update in Home Health Services.

Current Law

Home health service payments are increased on a federal fiscal year basis that begins in October. The FY 2004 statutory update would be the full increase in the market basket index.

Explanation of Provision

This provision would increase home health agency payments by the home health market basket percentage increase minus 0.4 percentage points for 2004 through 2006. The update for subsequent years would be the full market basket percentage increase. The provision would also change the time frame for the update from the federal fiscal year to a calendar year basis. The home health prospective payment rates would not increase for the October 1 through December 31, 2003, period.

Effective Date

Upon enactment

Reason for Change

The Medicare Payment Advisory Commission recommended that Congress should eliminate the update to payment rates for home health services for fiscal year 2004. The Medicare margins for all agencies are 23.3 percent, even given the October 1, 2003 reduction. The mb-0.4 provides substantial payment increases for home heath agencies. However, they would be lower than current law and would provide stability.

Section 702. Establishment of Reduced Copayment for a Home Health Service Episode of Care for Certain Beneficiaries.

Current Law

The home health benefit does not have any cost sharing requirement.

Explanation of Provision

This provision would establish a beneficiary copayment for each 60-day episode of care beginning January 1, 2004. The amount of the copayment would be 1.5 percent of the national average payment per episode in a calendar year, as projected by the Secretary before the beginning of the year. The copayment amount would be rounded to the nearest multiple of five dollars. For 2004, the copayment would be $40 unless the Secretary provides the results of the statutory formula in a timely manner. Medicare payment for each episode would be reduced to reflect the copayment amount. Qualified Medicare beneficiaries (low-income beneficiaries for whom Medicaid pays Medicare premiums, deductibles, and coinsurance), beneficiaries dually eligible for Medicare and Medicaid, and beneficiaries receiving five or fewer home health visits per episode of care would not face any cost-sharing requirements. Administrative and judicial review of the calculated copayment amounts would be prohibited.

Effective Date

Upon enactment.

Reason for Change

Unlike almost all Part B services, the Medicare home health benefit does not have a copayment. The typical beneficiary receives about $3,000 worth of free home health care (CBO estimate). At the same time, home health spending is increasing rapidly rising almost 13 percent a year between 2004 and 2012 (CBO). In fact, the Congressional Budget Office estimates home health spending will have almost tripled in size in that same period. When spending increases, so do beneficiary premiums because they are tied to program's costs.

Part of the reason for the spending increases it because it is difficult to determine if the beneficiary really needs home health (GAO and CMS). Requiring even nominal copays encourages beneficiaries to use care more prudently.

For the 90 percent of beneficiaries that have supplemental policies or other coverage, the Medicare program collects the copayments by automatically crossing over the claim to their insurance companies. Thus, the copayments generate little administrative cost for an agency.

Section 703. MedPAC Study of Medicare Margins of Home Health Agencies.

Current Law

No provision.

Explanation of Provision

The provision would require MedPAC to study payment margins of home health agencies paid under the Medicare prospective payment system. The study would examine whether systematic differences in payment margins were related to differences in case mix, as measured by home health resource groups (HHRGs). MedPAC would be required to submit a report to Congress on the study within two years of enactment.

Effective Date

Upon enactment.

Subtitle B – Direct Graduate Medical Education

Section 711. Extension of Update Limitation on High Cost Programs.

Current Law

Medicare pays hospitals for its share of direct graduate medical education (DGME) costs in approved programs using a count of the hospitals number of full-time equivalent residents and a hospital-specific historic cost per resident, updated for inflation. BBRA changed Medicare's methodology for calculating DGME payments to teaching hospitals to incorporate a new benchmark set at the national average amount based on FY1997 hospital specific per resident amounts. Starting in FY2001, hospitals received no less than 70 percent of a geographically adjusted national average amount. BIPA increased this floor to 85 percent of the locality adjusted, updated, and weighted national per resident amounts starting for cost report periods beginning during FY2002. Hospitals with per resident amounts above 140 percent of the geographically adjusted national average amount had payments frozen at current levels for FY2001 and FY2002, and in FY2003-FY2005 would receive an update equal to the Consumer Price Index (CPI) increase minus two percentage points. Currently, hospitals with per resident amounts between 85 percent and 140 percent of the geographically adjusted national average would continue to receive payments based on their hospital-specific per resident amounts updated for inflation.

Explanation of Provision

The hospitals with per resident amounts above 140 percent of the geographically adjusted national average amount would not get an update from FY2004 through FY2013.

Effective Date

Upon enactment

Reason for Change

The DGME amounts in these high cost hospitals are far higher that can be explained by the cost of living and legitimate difference in overhead. High quality medical training is delivered in most facilities for a fraction of the cost of high-cost institutions. The Medicare payments to these institutions have nothing to do with actual costs of training these physicians.

Subtitle C – Chronic Care Improvement

Section 721. Voluntary Chronic Care Improvement under Traditional Fee-For-Service.

Current Law

No provision.

Explanation of Provision

The Secretary would be required to establish a process for providing chronic care improvement programs for Medicare beneficiaries in FFS Medicare (Parts A and B) who have certain chronic conditions such as congestive heart failure, diabetes, chronic obstructive pulmonary disease, stroke or other diseases as identified by the Secretary. The Secretary would establish administrative regions, Chronic Care Improvement Administrative regions (CCIAs) within the United States for chronic care improvement programs. Within each CCIA, the Secretary would select at least two contractors under a competitive bidding process on the basis of the ability of each bidder to achieve improved health outcomes of the participating beneficiaries and improved financial outcomes of the Medicare program. A contractor would be a disease improvement organization, health insurer, provider organization, group of physicians, or any other legal entity that the Secretary determines appropriate. Contractors would be required to meet certain clinical, quality improvement, financial, and other requirements specified by the Secretary either directly or indirectly through the use of subcontractors. The Secretary would be able to phase-in implementation of the program beginning one-year after enactment.

Each program would be required to have a method for identifying targeted Medicare beneficiaries who would be offered participation in the program. The Secretary would be required to assist the program in identifying beneficiaries. Each beneficiary would be assigned to only one contractor that would be responsible for guiding beneficiaries in managing their health including all co-morbidities. Initial contact with a Medicare beneficiary would be from the Secretary who would provide information about the program, including a description of advantages in participating. The Secretary would inform the beneficiary that the contractor would contact the beneficiary directly concerning participation, the voluntary nature of program

participation, and a means of declining to participate or decline being contacted by the program. Each program would be required to develop an individualized, goal-oriented chronic care improvement plan with the beneficiary. The chronic care improvement plan would be required to contain: a single point of contact to coordinate care; self-improvement education for the individual and support education for health care providers, primary caregivers, and family members; coordination between prescription drug benefits, home health, and other health care services; collaboration with physicians and other providers to enhance communication of relevant clinical information; the use of monitoring technologies, where appropriate; and information about hospice care, pain and palliative care, and end-of-life care, as appropriate. In developing the chronic care improvement plan, programs would be required to use decision support tools such as evidence-based practice guidelines and a clinical information database to track and monitor each beneficiary across care settings and evaluate outcomes. The program would be required to meet any additional requirements that the Secretary finds appropriate. Programs would be accredited by qualified organizations to be deemed to have met such requirements as specified by the Secretary.

Contractor payments for each chronic care improvement program would be required to result in Medicare program outlays that would otherwise have been incurred in the absence of the program for the three-year contract period. The Secretary would be required to assure that there would be no net aggregate increase in Medicare payments, in entering into a contract for the program over the three-year period. Contracts for chronic care improvement programs would be treated as a risk-sharing arrangement. In addition, payment to contractors would be subject to the contractor meeting clinical and financial performance standards established by the Secretary.

Program contractors would be required to report to the Secretary on the quality of care and efficacy of the program in terms of process measures (such as reductions in errors and re-hospitalization rates), beneficiary and provider satisfaction, health outcomes, and financial outcomes. The Secretary would be required to submit to Congress annual reports on the program including information on progress made toward national coverage, common delivery models, and information on improvements in health outcomes, as well as financial efficiencies resulting from the program. The Secretary would also be required to conduct a randomized clinical trial to assess the potential for cost reductions under Medicare by comparing costs of beneficiaries enrolled in chronic care improvement programs and beneficiaries who are eligible to participate but are not enrolled.

Appropriations of such sums as necessary to provide for contracts with chronic care improvement programs would be authorized from the Medicare Trust Funds.

Effective Date

The provision would be effective upon enactment and the Secretary would be required to begin implementing the chronic care improvement programs no later than one-year after enactment.

Reason for Change

Under current law, FFS Medicare does not offer coordinated care programs for the chronically ill. Chronic care management is an important issue, because 84 percent of seniors have one or more chronic conditions. In addition, individuals with chronic conditions account for 80 percent of all health care spending, with two-thirds of Medicare spending being spent on seniors with five or more chronic conditions. CMS has run demonstration programs in the Medicare program, particularly for high cost or especially frail adults. CMS is currently managing more than a dozen demonstration programs on disease and case management. A permanent program should be established within FFS Medicare that offers chronic care management to high-cost chronically ill seniors.

Section 722. Chronic Care Improvement under Medicare Advantage and Enhanced Fee-For-Service Programs.

Current Law

Under the Medicare+Choice program, organizations are required to have quality assurance programs that include measuring outcomes, monitoring and evaluating high volume and high risk services and the care of acute and chronic conditions, and evaluating the effectiveness of the efforts.

Explanation of Provision

Each Medicare Advantage plan offered would be required to have a chronic care improvement program for enrollees with multiple or sufficiently severe chronic conditions such as congestive heart failure, diabetes, chronic obstructive pulmonary disease, stroke or other disease as identified by the Secretary. The program would be required to have a method for monitoring and identifying enrollees with multiple or sufficiently severe chronic conditions and to develop with an enrollee's consent an individualized, goal-oriented chronic care improvement plan.

The chronic care improvement plan would be required to include: a single point of contact to coordinate care; self-improvement education for the individual and support education for health care providers, primary caregivers, and family members; coordination between prescription drug benefits, home health, and other health care services; collaboration with physicians and other providers to enhance communication of relevant clinical information; the use of monitoring technologies, where appropriate; and information about hospice care, pain and palliative care, and end-of-life care, as appropriate. In developing the chronic care improvement plan, programs would be required to use decision support tools such as evidence-based practice guidelines and a clinical information database to track and monitor each beneficiary across care settings and evaluate health outcomes. The program would be required to meet any additional requirements that the Secretary finds appropriate. Programs that have been accredited by qualified organizations would be deemed to have met such requirements as specified by the Secretary.

Each Medicare Advantage organization would be required to report to the Secretary on the quality of care and efficacy of the chronic care improvement program.

Effective Date

The provision would apply for contract years beginning on or after one year after enactment.

Reason for Change

Many Medicare Health Maintenance Organizations (HMOs) already provide chronic care management programs. These programs target high-cost beneficiaries suffering from one or more chronic conditions and coordinate their care within plan. This requirement for private plans would continue the chronic care/disease management programs most Medicare HMOs already have in place.

Section 723. Institute of Medicine Report.

Current Law

No provision.

Explanation of Provision

The Secretary would be required to contract with the Institute of Medicine of the National Academy of Sciences to study the barriers to effective integrated chronic care improvement for Medicare beneficiaries with multiple or severe chronic conditions across settings and over time. The study would examine the statutory and regulatory barriers to coordinating care across settings for Medicare beneficiaries in transition from one setting to another. The Institute of Medicine would be required to submit the report of the study to the Secretary and Congress no later than 18 months after enactment.

Effective Date

Upon enactment.

Section 724. MedPAC Report.

Current Law

No provision.

Explanation of Provision

MedPAC would be required to evaluate the chronic care improvement program. The evaluation would include a description of the status concerning implementation of the program, the quality of health care services provided to individuals participating in the program, and the cost savings attributed to implementation. The report of the evaluation would be submitted to Congress not later than two years after implementation of the program.

Effective Date

Upon enactment.

Subtitle D – Other Provisions

Section 731. Modifications to MedPAC.

Current Law

The Medicare Payment Advisory Commission is a 17-member body that reports and makes recommendations to Congress regarding Medicare payment policies. The Comptroller General is required to establish a public disclosure system for Commissioners to disclose financial and other potential conflicts of interest.

Explanation of Provision

MedPAC would be required to examine the budgetary consequences of a recommendation before making the recommendation and to review the factors affecting the efficient provision of expenditures for services in different health care sectors under FFS Medicare. MedPAC would be required to submit two additional reports no later than June 1, 2003. The first report would study the need for current data, and the sources of current data available, to determine the solvency and financial circumstances of hospitals and other Medicare providers. MedPAC would be required to examine data on uncompensated care, as well as the share of uncompensated care accounted for by the expenses for treating illegal aliens. The second report would address investments and capital financing of hospitals participating under Medicare and access to capital financing for private and not-for-profit hospitals. The provision would also require that members of the Commission be treated as employees of Congress for purposes of financial disclosure requirements.

Effective Date

Upon enactment.

Reason for Change

Congress needs to ensure that the Commission remains the objective impartial agency that it is today. Moreover, the Commission cannot be removed from the same constraints that Congress itself must face through considerations of the budget.

Section 732. Demonstration Project for Medical Adult Day Care Services.

Current Law

No provision

Explanation of Provision

Subject to earlier provisions, the Secretary would be required to establish a demonstration project under which a home health agency, directly or under arrangement with a medical adult day care facility, provide medical adult day care services as a substitute for a portion of home health services otherwise provided in a beneficiary's home. Such services would have to be provided as part of a plan for an episode of care for home health services established for a beneficiary. Payment for the episode would equal 95 percent of the amount that would otherwise apply. In no case would the agency or facility be able to charge the beneficiary separately for the medical adult day care services. The Secretary would reduce payments made under the home health prospective payment system to offset any amounts spent on the demonstration project. The three-year demonstration project would be conducted at not more than five sites, selected by the Secretary, in states that license or certify providers of medical adult day care services. Participation of up to 15,000 Medicare beneficiaries would be on a voluntary basis.

When selecting participants, the Secretary would give preference to home health agencies that are currently licensed to furnish medical adult day care services and have furnished such services to Medicare beneficiaries on a continuous basis for a prior two-year period. A medical adult day care facility would: (1) have been licensed or certified by a State to furnish medical adult day care services for a continuous two-year period, (2) have been engaged in providing skilled nursing services or other therapeutic services directly or under arrangement with a home health agency, and (3) would meet quality standards and other requirements as established by the Secretary. The Secretary would be able to waive necessary Medicare requirements except that beneficiaries must be homebound in order to be eligible for home health services.

The Secretary would be required to evaluate the project's clinical and cost effectiveness and submit a report to Congress no later than 30 months after its commencement. The report would include: (1) an analysis of patient outcomes and comparative costs relative to beneficiaries who receive only home health services for the same health conditions, and (2) recommendations concerning the extension, expansion, or termination of the project.

Effective Date

Upon enactment

Reason for Change

This demonstration would test the delivery of home health services in a group setting. While many of these patients are very frail, social interaction may prove to have a clinical benefit. At the same time, the current quality standards remain for delivering home health care.

Section 733. Improvements in National and Local Coverage Determination Process To Respond to Changes in Technology.

Section 734. National and Local Coverage Determination Process.

Current Law

No provision.

Explanation of Provision

Subsection (a) would require the Secretary to make available to the public the general guidelines used in making national coverage determinations under Medicare. These determinations would be required to include the way in which the Secretary considers evidence to assess whether a procedure or device is reasonable or necessary. The provision would establish a time frame for decisions regarding national coverage determinations of six months after a request when a technology assessment is not required and 12 months when a technology assessment is required and in which a clinical trial is not requested. Following the six- or 12-month period, the Secretary would be required to make a draft of the proposed decision available in the HHS website or by other means; to provide a 30-day public comment period; to make a final decision on the request with 60 days following the conclusion of the public comment period; and make the clinical evidence and data used in making the decision available to the public. In instances where the Medicare Coverage Advisory Committee does not review a request for a national coverage determination, the Secretary would be required to consult with appropriate outside clinical experts.

The Secretary would also be required to develop a plan to evaluate new local coverage determinations to decide which local decisions should be adopted nationally and to decide to what extent greater consistency can be achieved among local coverage decisions, to require the Medicare contractors within an area to consult on new local coverage policies, and to disseminate information on local coverage determination among Medicare contractors to reduce duplication of effort.

Effective Date

The provision would be effective for determinations as of January 1, 2004.

Reason for Change

The General Accounting Office reported in April 2003 problems with both the national coverage and local coverage process. Even though CMS assigned a 90-day process for coverage decisions, the average time was seven months with several taking over a year. GAO recommended establishing new time frames and a public process. GAO also found the local coverage process resulted in inequities for beneficiaries and wasteful duplication of administrative costs.

(b) Medicare Coverage of Routine Costs Associated with Certain Clinical Trials.

Current Law

No provision.

Explanation of Provision

Subsection (b) would provide for the coverage of the routine costs of care for Medicare beneficiaries participating in clinical trials that are conducted in accordance with an investigational device exemption approved under section 530(g) of the Federal Food, Drug, and Cosmetic Act.

Effective Date

The provision would be effective for clinical trials begun before, on, or after the date of enactment and to items and services furnished on or after enactment.

Reason for Change

There is a discontinuity between the coverage of clinical trials using breakthrough devices and the coverage afforded other routine clinical trials. This provision would resolve this problem.

(c) Issuance of Temporary National Codes.

Current Law

The Secretary issues temporary national Health Care Common Procedure Coding System (HCPCS) codes under Medicare Part B that are used until permanent codes are established.

Explanation of Provision

Subsection (c) would require that the Secretary implement revised procedures for the issuance of temporary national HCPCS codes.

Effective Date

The provision would be effective not later than one year after enactment.

Reason for Change

Coding for HCPCs under Part B is a patchwork with temporary codes allowed for some services and not for others. This would create national uniformity.

Section 734. Extension of Treatment for Certain Physician Pathology Services Under Medicare.

Current Law

In general, independent laboratories cannot directly bill for the technical component of pathology services provided to Medicare beneficiaries who are inpatients or outpatients of acute care hospitals. BIPA permitted independent laboratories with existing arrangements with acute hospitals to bill Medicare separately for the technical component of pathology services provided to the hospitals' inpatients and outpatients. The arrangement between the hospital and the independent laboratory had to be in effect as of July 22, 1999. The direct payments for these services apply to services furnished during a two-year period starting on January 1, 2001 and ending December 31, 2002.

Explanation of Provision

Medicare would make direct payments for the technical component for these pathology services. A change in hospital ownership would not affect these direct billing arrangements.

Effective Date

Upon enactment.

Reason for Change

Many hospitals do not have on-site pathology services and this provision would continue the prior arrangements.

H. TITLE VIII – MEDICARE BENEFITS ADMINISTRATION

Section 801. Establishment of Medicare Benefits Administration.

Current Law

The authority for administering the Medicare program resides with the Secretary of Health and Human Services. The Secretary originally created the agency that administers the Medicare and Medicaid programs in 1977 under his administrative authority. Regulations

regarding Medicare are required to be promulgated by the Secretary. The Medicare statute requires the President to appoint the Administrator of CMS (formerly known as the Health Care Financing Administration) with the advice and consent of the Senate. Title V of the U.S. Codes sets the MBA Administrator's salary at level IV of the Executive Schedule. The Medicare statute requires the CMS Administrator to appoint a Chief Actuary who reports directly to such Administrator and receives pay at the highest rate of basic pay for the Senior Executive Service.

Explanation of Provision

The section would amend Title XVIII to add a new Section 1809 that, under subsection (a), would establish a new Medicare Benefits Administration (MBA) within the Department of Health and Human Services.

Subsection (b) would provide for an Administrator and Deputy Administrator of the MBA. The President with the advice and consent of the Senate would appoint both for 4-year terms. If a successor did not take office at the end of the term, the Administrator would continue in office until the successor enters the office. In that event, the confirmed successor's term would be the balance of the 4-year period. The Administrator would be paid at level III of the Executive Schedule and the Deputy Administrator at level IV of the Executive Schedule. The Administrator would be responsible for the exercise of all powers and the discharge of duties of the MBA and has authority and control over all personnel. The provision would permit the Administrator to prescribe such rules and regulations as the Administrator determined necessary or appropriate to carry out the functions of MBA, subject to the Administrative Procedure Act. The Administrator would be able to establish different organizational units within the MBA except for any unit, component, or provision specifically provided for by section 1809. The Administrator may assign duties, delegate, or authorize re-delegations of authority to MBA officers and employees as needed. The Secretary shall ensure appropriate coordination between the Administrators of MBA and CMS to administer the Medicare program. The provision also would establish a position of Chief Actuary within the MBA who would be appointed by the Administrator and paid at the highest rate of basic pay for the Senior Executive Service. The Chief Actuary would exercise such duties as are appropriate for the office of Chief Actuary and in accordance with professional standards of actuarial independence.

Subsection (c) would prescribe the duties of the Administrator and administrative provisions relating to the MBA. In administering parts C, D, and E of Medicare, the Administrator would be required to negotiate, enter into, and enforce contracts with PDP and MA-EFFS sponsors. The Administrator would be required to carry out any duty provided for under Part C, D, or E, including implementation of the prescription drug discount card program and demonstration programs (carried out in whole or in part under Part C, D, or E). The provision specifically prohibits the Administrator from requiring a particular formulary or instituting a price structure for the reimbursement of covered drugs; from interfering in any way with negotiations between PDP and MA-EFFS sponsors, drug manufacturers, wholesalers, or other suppliers of covered drugs; and from otherwise interfering with the competitive nature of providing prescription drug coverage. The Administrator would be required to submit a report to Congress and the President on the administration of parts C, D, and E during the previous year by not later than March 31 of each year.

The Administrator, with the approval of the Secretary, would be permitted to hire staff to administer the activities of MBA without regard to chapter 31 of title 5 of the U.S. Code B other than sections 3110, the prohibition against officials hiring relatives, and 3112, the hiring preferences given to veterans. The Administrator would be required to employ staff with appropriate and necessary experience in negotiating contracts in the private sector. The staff of MBA would be paid without regard to chapter 51 (other than section 5101 requiring classification of positions according to certain principles) and chapter 53 (other than section 5301 relating to the principles of pay systems) of title 5 of the U.S. Code. The rate of compensation for staff of MBA would not be able to exceed level IV of the Executive Schedule. The Administrator would be limited in the number of full-time-equivalent (FTEs) employees for the MBA to the number of FTEs within CMS performing the functions being transferred at the time of enactment. The Secretary, the Administrator of MBA, and the Administrator of CMS would be required to establish an appropriate transition of responsibility to re-delegate the administration of Medicare part C from CMS to MBA. The provision requires the Secretary to ensure that the Administrator of CMS transfers such information and data as the Administrator of MBA requires to carry out the duties of MBA.

Subsection (d) would require the Secretary to establish an Office of Beneficiary Assistance within MBA to coordinate Medicare beneficiary outreach and education activities, and provide Medicare benefit and appeals information to Medicare beneficiaries under parts C, D, and E.

Subsection (e) would establish the Medicare Policy Advisory Board (the Board) within the MBA to advise, consult with, and make recommendations to the Administrator regarding the administration and payment policies of parts C, D, and E. The Board would be required to report to Congress and to the Administrator of MBA such reports as the Board determines appropriate and may contain recommendations that the Board considers appropriate regarding legislative or administrative changes to improve the administration of parts C, D, and E including: increasing competition under part C, D, or E for services furnished to beneficiaries; improving efforts to provide beneficiaries information and education about Medicare, parts C, D, and E, and Medicare enrollment; evaluating implementation of risk adjustment under parts C and E; and improving competition and access to plans under parts C, D, and E. The reports would be required to be published in the *Federal Register*. The reports would be submitted directly to Congress and no officer or agency of the government would be allowed to require the Board to submit a report for approval, comments, or review prior to submission to Congress. Not later than 90 days after a report is submitted to the Administrator, the Administrator would be required to submit to Congress and the President an analysis of the recommendations made by the Board. The analysis would be required to be published in the *Federal Register*.

The Board would be made up of 7 members serving three-year terms, with three members appointed by the President, two appointed by the Speaker of the House of Representatives, and two appointed by the President pro tempore of the Senate. Board members may be reappointed but may not serve for more than 8 years. The Board shall elect the Chair to serve for three years. The Board is required to meet at least three times a year and at the call of the Chair.

The Board is required to have a director who, with the approval of the Board, may appoint staff without regard to certain sections of chapter 31 of title 5 of the United States Code (which addresses authority for employment). In addition, the director and staff may be paid without regard to certain provisions of chapter 51 and 53 of title 5 which are related to classification and pay rates and pay systems B although the rate of compensation is capped at level IV of the Executive Schedule. The Board may contract with and compensate government and private agencies or persons to carry out its duties without regard to section 3709 of the Revised Statutes (41 U.S.C. (5).

Subsection (f) authorizes an appropriation of such sums as are necessary from the Federal Hospital Insurance Trust Fund and from the Federal Supplementary Medical Insurance Trust Fund (including the Prescription Drug Account) to carry out section 1808.

Effective Date

The provision would be effective upon enactment; however, the enrollment and eligibility functions and implementation of parts C and E would be effective January 1, 2006.

Reason for Change

A new agency, the Medicare Benefits Administration, would provide a more flexible and contemporary structure that is citizen-centered, results-oriented, and market-based. The administration of Parts C, D, and E would be separated from the administration of other parts of Medicare to ensure appropriate conduct of those parts of Medicare involving contracts with private organizations.

Implementing the M+C program in the past, CMS's decisions have made it difficult for private plans to participate in the program. Indeed, CMS has an inherent conflict of interest in administering traditional FFS while regulating the private plans. Placing the administration of Parts C, D, and E under a new MBA would create an agency whose main responsibility is the implementation and operation of successful private plan programs that enhance beneficiary choice.

The MBA would reshape the federal bureaucracy to better coordinate health plans and the prescription drug benefit, and replace a current system that is inefficient and outdated.

Civil service law reforms would permit the MBA to hire the best possible staff, with private sector experience in negotiating with plans. The MBA would have the ability to create a modern workforce by paying for performance, disciplining bad workers without lengthy appeals, and hiring employees more quickly. These changes would promote general government efficiency.

(c) Miscellaneous Administrative Provisions.

Current Law

The Board of Trustees of the Medicare Trust Funds is composed of the Commissioner of Social Security, the Secretary of the Treasury, the Secretary of Labor, and the Secretary of Health and Human Services and two members of the public. The Administrator of the Centers for Medicare & Medicaid Services serves as the Secretary of the Board of Trustees.

Title 5 of the U.S. Code sets the Administrator's salary at level IV of the Executive Schedule.

Explanation of Provision

Paragraph (1) would add the Administrator of MBA as an ex officio member of the Board of Trustees of the Medicare Trust Funds.

Paragraph (2) would increase the pay level for the Administrator of CMS from level IV of the Executive Schedule to level III.

Effective Date

Upon enactment.

Reason for Change

The Administrator of the MBA should be a member of the Board of Trustees to represent that part of Medicare involving contracts with private entities. The Administrator of CMS should be paid at the same level as the Administrator of the MBA.

I. TITLE IX – REGULATORY RELIEF

Subtitle A – Regulatory Reform

Section 901. Construction; Definition of Supplier.

Current Law

Section 1861 of the Social Security Act contains definitions of services, institutions, and so forth under Medicare. Supplier is not explicitly defined.

Explanation of Provision

Nothing in this title would be construed as compromising or affecting existing legal remedies for addressing fraud or abuse, whether it be criminal prosecution, civil enforcement or administrative remedies (including the False Claims Act) or to prevent or impede HHS from its

efforts to eliminate waste, fraud, or abuse in Medicare. The provision also would clarify that consolidation of the Medicare administrative contractors does not consolidate the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund. The provision would also clarify that the term. A supplier means a physician or other practitioner, a facility or other entity (other than a provider of services) furnishing items or services under Medicare.

Effective Date

Upon enactment.

Reason for Change

The Committees are committed to extending needed regulatory relief to providers and suppliers while at the same time protecting taxpayers from waste, fraud and abuse.

Section 902. Issuance of Regulations.

Current Law

The Secretary must publish a list of all manual instructions, interpretative rules, statements of policy, and guidelines that are promulgated to carry out Medicare law in the *Federal Register* no less frequently than every three months.

There is no explicit statutory instruction on logical outgrowth. The courts have repeatedly held that new matter in final regulations must be a logical outgrowth of the proposed rule and is an inherent aspect of notice and comment rulemaking.

Explanation of Provision

The provision would require the Secretary, in consultation with the Director of the Office of Management and Budget, to establish and publish a regular timeline for the publication of final regulations based on the previous publication of a proposed rule or an interim final regulation. The timeframe established would not be permitted to be longer than three years, except under extraordinary circumstances. If the Secretary were to vary the timeline he established, the provision would require him to publish a notice in the *Federal Register* the new timeline and an explanation of the variation. In the case of interim final regulations, the provision would require that if the Secretary did not meet his established timeframe, then the interim final regulation would not be able to continue in effect unless the Secretary published a notice of continuation of the regulation that included an explanation of why the regular timeline had not been complied with.

The provision also would require that a provision of a final regulation that is not a logical outgrowth of the proposed regulation or interim final regulation would be treated as a proposed regulation. The provision would not be able to take effect until public comment occurred and the provision published as a final regulation.

Effective Date

The provision regarding the establishment of regulatory timeframes would be effective upon enactment and would require the Secretary to provide for an appropriate transition to take into account the backlog of previously published interim final regulation. The provision regarding logical outgrowth would be effective for final regulations published on or after enactment.

Reason for Change

The volume of Medicare regulations issued by CMS can be difficult for health care providers and suppliers, particularly small providers and suppliers, to monitor. By requiring regulations to be released on a certain date, providers and suppliers would be better able to keep informed of program changes. The Secretary may stagger the notice and comment periods of regulations issued on the same day, so that the comment deadlines for these regulations do not occur simultaneously, in order to ensure that interested parties have the opportunity to comment on multiple regulations.

The collective impact provision ensures that the Department would consider the overall impact of any changes it is making on categories of providers and suppliers. If the Department determines that many changes affecting a particular category of providers or suppliers are underway, the Department should consult with representatives of that category to determine whether providers and suppliers would be better able to make the systems changes needed to accommodate those changes if all the new regulations were released simultaneously or staggered. Because of the burden implementing multiple regulations simultaneously can cause, the Secretary needs to coordinate new regulations based on an analysis of the collective impact the regulatory changes will have on any given category of provider or supplier.

Section 903. Compliance with Changes in Regulations and Policies.

Current Law

No explicit statutory instruction. As a result of case law, there is a strong presumption against retroactive rulemaking. In *Bowen v. Georgetown University Hospital*, the Supreme Court ruled that there must be explicit statutory authority to engage in retroactive rulemaking.

Explanation of Provision

The provision would bar retroactive application of any substantive changes in regulation, manual instructions, interpretative rules, statements of policy, or guidelines unless the Secretary determines retroactive application is needed to comply with the statute or is in the public interest. No substantive change would go into effect until 30 days after the change is issued or published unless it would be needed to comply with statutory changes or was in the public interest. Compliance actions would be able to be taken for items and services furnished only on or after the effective date of the change. If a provider or supplier follows written guidance provided by

the Secretary or a Medicare contractor when furnishing items or services or submitting a claim and the guidance is inaccurate, the provider or supplier would not be subject to sanction or repayment of overpayment (unless the inaccurate information was due to a clerical or technical operational error).

Effective Date

The prohibition of retroactive application of substantive changes would apply to changes issued on or after the date of enactment. The provisions affecting compliance with substantive changes would apply to compliance actions undertaken on or after the date of enactment. The reliance on guidance would take effect upon enactment but would not apply to any sanction for which notice was provided on or before the date of enactment.

Reason for Change

This provision would ensure that Medicare's rules are not generally applied retroactively. It would also ensure providers and suppliers have sufficient time to make any changes to systems needed to comply with changes in regulations. This provision would ensure that providers and suppliers, who, in good faith, based on the information received from contractors, would not be vulnerable to recovery if it turns out that the contractor was in error. Providers should be able to rely on the directions or guidance provided by their Medicare contractors.

Section 904. Reports and Studies Relating to Regulatory Reform.

Current Law

No provision.

Explanation of Provision

The GAO would be required to study the feasibility and appropriateness of the Secretary providing legally binding advisory opinions on appropriate interpretation and application of Medicare regulations. The report would be due to Congress one year after enactment.

The Secretary would be required to report to Congress every two years on the administration of Medicare and areas of inconsistency or conflict among various provisions under law and regulation. The report would include recommendations for legislation or administrative action that the Secretary determines appropriate to further reduce such inconsistency or conflicts. The first report would be due to Congress two years after enactment.
Effective Date

Upon enactment.

Reason for Change.

The Committees are interested in receiving additional information regarding both advisory opinions and inconsistencies in Medicare regulations.

Subtitle B – Contracting Reform

Section 911. Increased Flexibility in Medicare Administration.

Current Law

The Secretary is authorized to enter into agreements with fiscal intermediaries nominated by different provider associations to make Medicare payments for health care services furnished by institutional providers. For Medicare part B claims, the Secretary is authorized to enter into contracts only with health insurers (or carriers) to make Medicare payments to physicians, practitioners and other health care suppliers. Section 1834(a)(12) of the Act authorizes separate regional carriers for the payment of durable medical equipment (DME) claims. The Secretary is also authorized to contract for certain program safeguard activities under the Medicare Integrity Program (MIP).

Certain terms and conditions of the contracting agreements for fiscal intermediaries (FIs) and carriers are specified in the Medicare statute. Medicare regulations coupled with long-standing agency practices have further limited the way that contracts for claims administration services can be established.

Certain functions and responsibilities of the fiscal intermediaries and carriers are specified in the statute as well. The Secretary may not require that carriers or intermediaries match data obtained in its other activities with Medicare data in order to identify beneficiaries who have other insurance coverage as part of the Medicare Secondary Payer (MSP) program. With the exception of prior authorization of DME claims, an entity may not perform activities (or receive related payments) under a claims processing contract to the extent that the activities are carried out pursuant to a MIP contract. Performance standards with respect to the timeliness of reviews, fair hearings, reconsiderations and exemption decisions are established as well.

A Medicare contract with an intermediary or carrier may require any of its employees certifying or making payments provide a surety bond to the United States in an amount established by the Secretary. Neither the contractor nor the contractor's employee who certifies the amount of Medicare payments is liable for erroneous payments in the absence of gross negligence or intent to defraud the United States. Neither the contractor nor the contractor's employee who disburses payments is liable for erroneous payments in the absence of gross negligence or intent to defraud the United States, if such payments are based upon a voucher signed by the certifying employee.

Explanation of Provision

This provision would add Section 1874A to the Social Security Act and would permit the Secretary to competitively contract with any eligible entity to serve as a Medicare contractor. The provision would eliminate the distinction between Part A contractors (fiscal intermediaries) and Part B contractors (carriers) and take the separate authorities for fiscal intermediaries and carriers and merge them into a single authority for the new contractor. These new contractors would be called Medicare Administrative Contractors (MACs) and would assume all the functions of the current fiscal intermediaries and carriers: determining the amount of Medicare payments required to be made to providers and suppliers, making the payments, providing education and outreach to beneficiaries, providers and suppliers, communicating with providers and suppliers, and additional functions as are necessary.

The Secretary would be permitted to renew the MAC contracts annually for up to 5 years. All contracts would be required to be re-competed at least every 5 years using competitive processes. Federal Acquisition Regulations (FAR) would apply to these contracts except to the extent any provisions are inconsistent with a specific Medicare requirement, including incentive contracts. The contracts would be required to contain performance requirements that would be developed by the Secretary who could consult with beneficiary, provider, and supplier organizations, would be consistent with written statements of work and would be used for evaluating contractor performance. MAC would be required to furnish the Secretary such timely information as he may require and to maintain and provide access to records the Secretary finds necessary. The Secretary could require a surety bond from the MAC or certain officers or employees as the Secretary finds appropriate. The Secretary would be prohibited from requiring that the MAC match data from other activities for Medicare secondary payer purposes.

The provision would limit liability of certifying and disbursing officers and the Medicare Administrative Contractors except in cases of reckless disregard or the intent to defraud the United States. This limitation on liability would not limit liability under the False Claims Act. The provision also establishes circumstances where contractors and their employees would be indemnified, both in the contract and as the Secretary determines appropriate.

The provision would make numerous conforming amendments as the authorities for the fiscal intermediaries and carriers are stricken.

The Secretary would be required to submit a report to Congress and the GAO by no later than October 1, 2004, that describes the plan for implementing these provisions. The GAO is required to evaluate the Secretary's plan and, within six months of receiving the plan, report on the evaluation to Congress and make any recommendations the Comptroller General believes appropriate. The Secretary is also required to report to Congress by October 1, 2008 on the status of implementing the contracting reform provisions including the number of contracts that have been competitively bid, the distribution of functions among contracts and contractors, a timeline for complete transition to full competition, and a detailed description of how the Secretary has modified oversight and management of Medicare contractors to adapt to full competition.

Competitive bidding for the MACs would be required to begin for annual contract periods that begin on or after October 1, 2011.

Effective Date

Upon enactment.

Reason for Change.

Medicare's current contracting represents an antiquated, inefficient, and closed system based on cozy relationships between the government, contractors and providers.

Medicare contracting is antiquated because contractors may not provide service for the entire Medicare program, or particular functions within the program; rather Fiscal Intermediaries administer claims for facilities and carriers administer claims for all other providers. It has failed to keep pace with integrated claims administration practices in the private sector.

Medicare contracting is inefficient because Medicare does not award contracts through competitive procedures, but rather on provider nomination.

Medicare contracting is closed. All but one of the contractors today have been with Medicare since the program's inception 36 years ago, and only insurers can provide contracting services.

This provision permits greater flexibility in contracting for administrative services between the Secretary and the Medicare contractors (entities that process claims under part A and part B of the Medicare program), including the flexibility to separately contract for all or parts of the contractor functions. The Secretary also may contract with a wider range of entities, so that the most efficient and effective contractor can be selected.

These amendments require the Secretary to contract competitively at least once every five years for the administration of benefits under parts A and B. In conjunction with the elimination of cost contracts, it is intended to create incentives for improved service to beneficiaries and to providers of services and suppliers.

These amendments provide a basis for a unified contracting system for the administration of parts A and B, identical to the recent Congressionally mandated structure of the Medicare Integrity Program contractors. Consolidation of contracting duties as set forth in this legislation does not constitute consolidation of the Hospital Insurance and Medical Supplementary Insurance Trust Funds, or reflect any position on that issue. In addition, the elimination of provider nomination, which hospitals have rarely been allowed to exercise in recent years, is essential for bringing full and open competition into the contracting functions of the Medicare program.

The provision establishes a basis for a unified contracting system, identical to the structure implemented for the Medicare Integrity Program contractors. It is important to note,

however, that consolidation of contracting duties as set forth in this legislation does not constitute consolidation of the Hospital Insurance and Medical Supplementary Insurance Trust Funds, or reflect any position on that issue. In addition, the Secretary would have the flexibility to choose the best contractor(s) to provide telephone information on suppliers, which is intended to reduce administrative costs and improve quality. Since the carrier fair hearing requirement was eliminated in previous legislation, the requirements for the hearing are eliminated in order to conform to existing law.

Section 912. Requirements for Information Security for Medicare Administrative Contractors.

Current Law

No provision.

Explanation of Provision

Medicare administrative contractors (as well as fiscal intermediaries and carriers until the MACs are established) would be required to implement a contractor-wide information security program to provide information security for the operation and assets of the contractor for Medicare functions. The information security program would be required to meet certain requirements for information security programs imposed on Federal agencies under title 44 of the United States Code. Medicare administrative contractors would be required to undergo an annual independent evaluation of their information security programs. Existing contractors would be required to undergo the first independent evaluation within one year after the date the contractor begins implementing the information security program and new contractors would be required to have such a program in place before beginning the claim determination and payment activities. The results of the independent evaluations would be submitted to the Secretary and the HHS Inspector General. The Inspector General of HHS would be required to report to Congress annually on the results of the evaluations. The Secretary would be required to address the results of the evaluations in required management reports.

Effective Date

Upon enactment.

Reason for Change

The increased reliance by the Federal government on the Internet and related telecommunications technologies has resulted in enhanced inter-connectivity and interdependencies associated with Federal computer systems and between federal and private computer systems. Over the past several years, this inter-connectivity or networking has resulted in increased security vulnerabilities that have put at greater risk computer systems and data that are critical to ensuring national and economic security and public health and welfare, including sensitive, non-public information that is collected and maintained by CMS and its business partners.

On May 23, 2001, the Committee on Energy and Commerce held a hearing to investigate the extent to which sensitive, non-public information related to collecting and processing Medicare claims was adequately secure on the computer networks operated by CMS and its business partners, including Medicare contractors. That investigation revealed significant weaknesses, which the agency has been working to address. Some of the computer security concerns identified include weak password management, inadequate access controls, excessive user privileges, improper network configurations, and inadequate testing of critical systems. In addition, the OIG conducted assessments of financial controls—including electronic data processing controls—at CMS and its major Medicare contractors; in every year since 1997, the OIG has identified computer security controls as a material weakness at CMS and its contractors.

Section 812 is intended to assist CMS in identifying and working with contractors to address potential security deficiencies in order to ensure that sensitive, non-public information related to the processing of Medicare claims is adequately secure from unauthorized access, misuse, or destruction.

Subtitle C – Education and Outreach

Section 921. Provider Education and Technical Assistance.

(a) Coordination of Education Funding.

Current Law

Medicare provider education activities are funded through the program management appropriation and through Education and Training component of the Medicare Integrity Program (MIP). Both claims processing contractors (fiscal intermediaries and carriers) and MIP contractors may undertake provider education activities.

Explanation of Provisions

The provision would add Section 1889 to the Social Security Act, which would require the Secretary to coordinate the educational activities through the Medicare contractors to maximize the effectiveness of education efforts for providers and suppliers and to report to Congress with a description and evaluation of the steps taken to coordinate provider education funding.

Effective Date

Upon enactment.

Reason for Change

This provision is intended to ensure that federal spending on provider education is coordinated and used as efficiently as possible to maximize the value obtained from the investment. It is not intended to change the proportion of Medicare Integrity Program funds spent on provider education.

(b) Incentives to Improve Contractor Performance.

Current Law

No specific statutory provision. Since FY1996, as part of the audit required by the Chief Financial Officers Act, an annual estimate of improper payments under FFS has been established. As a recent initiative, CMS is implementing a comprehensive error rate-testing program to produce national, contractor specific, benefit category specific and provider specific paid claim error rates.

Explanation of Provisions

The Secretary would be required to use specific claims payment error rates (or similar methodology) to provide incentives for contractors to implement effective education and outreach programs for providers and suppliers and would require the Comptroller General to study the adequacy of the methodology and make recommendations to the Secretary and the Secretary to report to Congress regarding how he intends to used the methodology in assessing Medicare contractor performance.

Effective Date

Upon enactment.

Reason for Change

This provision would ensure that the Department monitors contractor performance for claims payment error rates, and it would identify best practices for provider education - all with the goal of reducing payment errors and helping providers and suppliers better comply with program requirements. It is the Committees' intent that, in consultation with representatives of providers and suppliers, the Secretary shall identify and encourage best practices developed by contractors for educating providers and suppliers.

(c) Provision of Access to and Prompt Responses from Medicare Administrative Contractors.

Current Law

No specific statutory provision. Statutory provisions generally instruct carriers to assist providers and others who furnish services in developing procedures relating to utilization

practices and to serve as a channel of communication relating information on program administration. Fiscal intermediaries are generally instructed to: (1) provide consultative services to institutions and other agencies to enable them to establish and maintain fiscal records necessary for program participation and payment, and (2) serve as a center for any information as well as a channel for communication with providers.

Explanation of Provisions

The Secretary would be required to develop a strategy for communicating with beneficiaries, providers and suppliers. Medicare contractors would be required to provide responses to written inquiries that are clear, concise and accurate within 45 business days of the receipt of the inquiry. The Secretary would be required to ensure that Medicare contractors have a toll-free telephone number where beneficiaries, providers and suppliers may obtain information regarding billing, coding, claims, coverage, and other appropriate Medicare information. Medicare contractors would be required to maintain a system for identifying the person supplying information to beneficiaries, providers and supplier and to monitor the accuracy, consistency, and timeliness of the information provided. The Secretary would be required to establish and make public standards to monitor the accuracy, consistency, and timeliness of written and telephone responses of Medicare contractors as well as to evaluate the contractors against these standards.

Effective Date.

The provision would be effective October 1, 2004.

Reason for Change

This provision is intended to improve contractor accountability to make contractors more responsive to providers and suppliers, and to increase the accuracy and reliability of the information provided in response to the questions received.

(d) Improved Provider Education and Training.

Current Law

In FY2003, approximately $122 million was budget by CMS for provider education and training.

Explanation of Provision

The provision would authorize $25 million to be appropriated from the Medicare Trust Funds for fiscal years 2005 and 2006, and such sums as necessary for succeeding fiscal years for Medicare contractors to increase education and training activities for providers and suppliers. Medicare contractors would be required to tailor education and training activities to meet the special needs of small providers or suppliers. The provision defines a small provider as an

institution with fewer than 25 full-time equivalents (FTEs) and a small supplier as one with fewer than 10 FTEs.

Effective Date

Upon enactment.

Reason for Change

This provision acknowledges that contractors are being instructed to significantly improve their provider education and training efforts, and accordingly authorizes new funds to be available for those purposes.

(e) Requirement to Maintain Internet Sites.

Current Law

No statutory provision. CMS and Medicare contractors currently maintain Internet sites.

Explanation of Provision

The provision would require that the Secretary and the Medicare contractors maintain Internet sites to answer frequently asked questions and provide published materials of the contractors beginning October 1, 2004.

Effective Date

The provision would be effective October 1, 2004.

Reason for Change

This provision would facilitate greater ease of provider and supplier access to information provided by Medicare's contractors.

(f) Additional Provider Education Provisions.

Current Law

No provision.

Explanation of Provision

The provision would bar Medicare contractors from using a record of attendance (or non-attendance) at educational activities to select or track providers or suppliers in conducting any type of audit or prepayment review.

Effective Date

Upon enactment.

Reason for Change.

This provision addresses a concern raised by providers and suppliers that their participation in educational forums has been used to trigger audits. Participation in educational forums should be encouraged not discouraged.

Nothing in this section or section 1893(g) shall be construed as preventing the disclosure by a Medicare contractor of information on attendance at education activities for law enforcement purposes. Nothing in this section or section 1893(g) shall be construed as providing for the disclosure by a Medicare contractor of the claims processing screens or computer edits used for identifying claims that would be subject to review.

Section 922. Small Provider Technical Assistance Demonstration Program.

Current Law

No provision.

Explanation of Provision

The Secretary would be required to establish a demonstration program to provide technical assistance to small providers and suppliers, when they have requested the assistance, to improve compliance with Medicare requirements. If errors are found, the Secretary would be barred from recovering any overpayments barring evidence of fraud and if the problem that is the subject of the compliance review has been satisfactorily corrected within 30 days and the problem remains corrected. A GAO study is required not later than two years after the demonstration program begins. Appropriations would be authorized for $1 million for FY 2005 and $6 million for FY 2006 to carry out the demonstration.

Effective Date

Upon enactment.

Reason for Change

Many large providers and suppliers have contracts with private consulting firms to help them navigate their interactions with the Medicare program. This type of assistance can be prohibitively expensive for small providers and suppliers - but they too are required to comply with complex program rules and regulations. This provision creates a new demonstration program to facilitate small provider and supplier access to expert technical assistance. The demonstration would also test whether encouraging technical assistance on the front-end (to help

providers and suppliers play by the rules) could save the program money in the long-term by promoting greater program compliance.

Section 923. Medicare Provider Ombudsman; Medicare Beneficiary Ombudsman.

Current Law

No provision.

Explanation of Provision

A Medicare Provider Ombudsman would be required to be appointed by the Secretary and located within the Department of Health and Human Services. The Provider Ombudsman would be required to provide confidential assistance to providers and suppliers regarding complaints, grievances, requests for information, and resolution of unclear or conflicting guidance about Medicare. The Ombudsman would submit recommendations to the Secretary regarding improving the administration of Medicare, addressing recurring patterns of confusion under Medicare, and ways to provide for an appropriate and consistent response in cases of self-identified overpayments by providers and suppliers. Such sums as necessary would be authorized to be appropriated for FY2004 and subsequent years.

A Medicare Beneficiary Ombudsman would be required to be appointed by the Secretary and located within HHS. The Beneficiary Ombudsman would be required to have expertise and experience in health care, education of, and assistance to Medicare beneficiaries. The Beneficiary Ombudsman would be required to receive complaints, grievances, and requests for information submitted by Medicare beneficiaries. The Beneficiary Ombudsman would also be required to assist beneficiaries in collecting relevant information to seek an appeal of a decision or determination made by the Secretary, a Medicare contractor, or a Medicare+Choice organization and assisting a beneficiary with any problems arising from un-enrolling in a Medicare+Choice plan. The Beneficiary Ombudsman would be required to work with state health insurance counseling programs.

Appropriations would be authorized to be appropriated in such sums, as are necessary for fiscal year 2004 and each succeeding fiscal year to carry out the ombudsmen provisions.

This provision would also require the use of 1-800-Medicare for all individuals seeking information about, or assistance with Medicare. Rather than listing individual telephone numbers for Medicare contractors in the Medicare handbook, only 1-800-Medicare would be shown. The Comptroller General would be required to study the accuracy and consistency of information provided by the 1-800-Medicare line and to assess whether the information sufficiently answers the questions of beneficiaries. The report on the study would be required to be submitted to Congress no later than one year after enactment.

Effective Date

The Secretary would be required to appoint both ombudsmen no later than one year from the date of enactment.

Reason for Change

Providers are currently confronted with a morass of bureaucracy and regulation, with no clear individual to assist them. The new ombudsman would help providers navigate Medicare's complicated rules and regulations.

Medicare Provider Ombudsman shall make recommendations to the Secretary concerning how to respond to recurring patterns of confusion in the Medicare program. Such a recommendation may include calling for the suspension of the imposition of provider sanctions (except those sanctions relating to the quality of care) or where there is widespread confusion in program administration. Nothing in this section shall be construed as allowing for the suspension of provider sanctions relating to the quality of care, regardless of whether widespread confusion in the Medicare program exists.

Beneficiaries confront a morass of bureaucracy and regulation, with no clear individual to assist them. This new ombudsman would help beneficiaries navigate Medicare's complicated rules and regulations.

The Committees acknowledge that implementing these new functions would have a cost and have accordingly authorized necessary appropriations.

The beneficiary handbook currently provides a multitude of phone numbers, which is very confusing for beneficiaries, rather than a single number that can triage and transfer beneficiaries to the appropriate person or entity. This provision would promote better access to information for beneficiaries.

Section 924. Beneficiary Outreach Demonstration Program.

Current Law

No provision.

Explanation of Provision

Subsection (a) would require the Secretary to conduct a three-year demonstration program where Medicare specialists would provide assistance to beneficiaries in at least six local Social Security offices (two would be located in rural areas) that have a high volume of visits by Medicare beneficiaries. The Secretary would be required to evaluate the results of the demonstration regarding the feasibility and cost-effectiveness of permanently out-stationing Medicare specialists at local Social Security offices and report to Congress.

Subsection (b) would require that the Secretary establish a demonstration project to test the administrative feasibility of providing a process for Medicare beneficiaries, providers, suppliers and other individuals or entities furnishing items or services under Medicare to request and receive a determination as to whether the item or service is covered under Medicare by reasons of medical necessity, before the item or service involved is furnished to the beneficiary. The Secretary would be required to evaluate the demonstration and report to Congress by January 1, 2006.

Effective Date

Upon enactment.

Reason for Change.

This provision makes Medicare experts available in six Social Security Administration offices to assist beneficiaries and answer their questions. The demonstration would test whether such outsourced Medicare specialists improve beneficiary utilization, understanding of the program, and beneficiary satisfaction.

Section 925. Inclusion of Additional Information in Notices to Beneficiaries about Skilled Nursing Facility Benefits.

Current Law

Although the statute requires that beneficiaries receive a statement listing the items and services for which payment has been made, there is no explicit statutory instruction that requires the notice to include information about the number of days of coverage remaining in either the hospital or skilled nursing facility (SNF) benefit or the spell of illness.

Explanation of Provision

The Secretary would be required to provide information about the number of days of coverage remaining under the SNF benefit and the spell of illness involved in the explanation of Medicare benefits.

Effective Date

The provision would apply to notices provided on and after the calendar quarter beginning more than six months after enactment.

Section 926. Information on Medicare-Certified Skilled Nursing Facilities in Hospital Discharge Plans.

Current Law

The hospital discharge planning process requires evaluation of a patient's likely need for post-hospital services including hospice and home care.

Explanation of Provision

The Secretary would be required to make information publicly available regarding whether SNFs are participating in the Medicare program. Hospital discharge planning would be required to evaluate a patient's need for SNF care.

Effective Date

The provision would apply to discharge plans made on or after the date specified by the Secretary, but no later than six months after the Secretary provides information regarding SNFs that participate in the Medicare program.

Subtitle D – Appeals and Recovery

Section 931. Transfer of Responsibility for Medicare Appeals.

Current Law

Denials of claims for Medicare payment may be appealed by beneficiaries (or providers who are representing the beneficiary) or in certain circumstances, providers or suppliers directly. The third level of appeal is to an Administrative Law Judge (ALJ). The Social Security Administration employs ALJs that hear Medicare cases, a legacy from the inception of the Medicare program, when Medicare was part of Social Security.

Explanation of Provision

The Commissioner of SSA and the Secretary would be required to develop a plan to transfer the functions of the ALJs who are responsible for hearing Medicare cases from SSA to HHS. This plan would be due to Congress no later than October 1, 2004. A GAO evaluation of the plan would be due within six months of the plan's submission. ALJ functions would be transferred no earlier than July 1, 2005 and no later than October 1, 2005.

The Secretary would be required to place the ALJs in an administrative office that is organizationally and functionally separate from the Centers for Medicare & Medicaid Services and the ALJs would be required to report to, and be under the general supervision of the Secretary. No other official within the Department would be permitted to supervise the ALJs. The Secretary would be required to provide for appropriate geographic distribution of ALJs,

would have the authority to hire ALJs and support staff, and would be required to enter into arrangements with the Commissioner, as appropriate, to share office space, support staff and other resources with appropriate reimbursement.

Such sums are authorized to be appropriated as are necessary for FY2005 and each subsequent fiscal year to increase the number of ALJs, improve education and training of ALJs and to increase the staff of the Departmental Appeals Board (the final level of appeal).

Effective Date

Upon enactment.

Reason for Change

The Office of Inspector General has identified moving the functions of the Medicare Administrative Law Judges to the Department of Health and Human Services as an important priority in improving the appeals system. This provision makes that transition and increases the emphasis on providing training Administrative Law Judges and their staffs to increase their expertise in Medicare's rules and regulations. The Commissioner of SSA and the Secretary are instructed to work together on the transition plans in order to assure that the transition does not adversely affect the SSA ALJ appeals system.

The transition plan shall include information on the following:

- Workload - The number of such administrative law judges and support staff required now and in the future to hear and decide such cases in a timely manner, taking into account the current and anticipated claims volume, appeals, number of beneficiaries, and statutory changes;
- Cost Projections - Funding levels required under this subsection to hear such cases in a timely manner;
- Transition Timetable - A timetable for the transition;
- Regulations - The establishment of specific regulations to govern the appeals process;
- Case Tracking - The development of a unified case tracking system that will facilitate the maintenance and transfer of case-specific data across both the fee-for-service and managed care components of the Medicare program;
- Feasibility of Precedential Authority - The feasibility of developing a process to give binding, precedential authority to decisions of the Departmental Appeals Board in the Department of Health and Human Services that address broad legal issues; and,
- Access to Administrative Law Judges - The feasibility of filing appeals with administrative law judges electronically, and the feasibility of conducting hearings using tele- or videoconference technologies.

Section 932. Process for Expedited Access to Review.

Current Law

In general, administrative appeals must be exhausted prior to judicial review.

Explanation of Provision

The Secretary would be required to establish a process where a provider, supplier, or a beneficiary may obtain access to judicial review when a 3-member review panel (composed of ALJs, members of the Departmental Appeals Board, or qualified individuals from qualified independent contractors designated by the Secretary) determines, within 60 days of a complete written request, that it does not have the authority to decide the question of law or regulation and where material facts are not in dispute. The decision would not be subject to review by the Secretary. Interest would be assessed on any amount in controversy and would be awarded by the reviewing court in favor of the prevailing party. This expedited access to judicial review would also be permitted for cases where the Secretary does not enter into or renew provider agreements.

Expedited review would also be established for certain remedies imposed against SNFs including denied payments and imposition of temporary management. The Secretary would be required to develop a process for reinstating approval of nurse aide training programs that have been terminated (before the end of the mandatory two-year disapproval period). The appropriation of such sums as needed for FY2005 and subsequent years would be authorized to reduce by 50 percent the average time for administrative determinations, to increase the number of ALJs and appellate staff at the DAB, and to educate these judges and their staffs on long-term care issues.

Effective Date

This provision would be effective for appeals filed one or after October 1, 2004.

Reason for Change.

The provisions in 402 (a-c) on expedited access to judicial review ensure that if a review board certifies that there are no material facts in dispute and that the appeals process does not have authority to resolve the question at issue, the provider, supplier, or beneficiary may take their case to court in an expedited manner. This would facilitate more prompt resolution of challenges to the underlying validity of CMS regulations and determinations. To the extent that any part of an appeal poses a factual dispute that is being adjudicated before an administrative tribunal, this provision would not authorize the severance of the legal issues from the underlying factual dispute.

Section 933. Revisions to Medicare Appeals Process.

(a) Requiring Full and Early Presentation of Evidence.

Current Law

No provision. New evidence can be presented at any stage of the appeals process.

Explanation of Provision

The provision would require providers and suppliers to present all evidence at the reconsideration that is conducted by a QIC unless good cause precludes the introduction of the evidence.

Effective Date

October 1, 2004.

Reason for Change.

The Office of Inspector General identified this change as a priority to promote more expeditious resolution of appeals of denied claims. This provision requires prompt introduction of evidence relevant to a provider appeal. When deciding whether there is good cause to introduce new evidence, the adjudicator should ensure, after consideration of the totality of the circumstances that disallowing the introduction of such new evidence would unfairly prejudice the case. The totality of the circumstances may include, but is not limited to, the following: evidence is not yet available; the appellant was not represented at a lower level of appeal; the appellant was not aware of her rights; or the appellant did not understand the proceeding.

(b) Use of Patients' Medical Records.

Current Law

No provision.

Explanation of Provision

The provision would provide for the use of beneficiaries' medical records in qualified independent contractors reconsiderations.

Effective Date

Upon enactment.

Reason for Change

In the determination of whether an item or service is reasonable and necessary for an individual, a beneficiary's medical records should be considered with other relevant information.

(c) Notice Requirements for Medicare Appeals.

Current Law

No statutory provision. Determinations and denials of appeals currently include the policy, regulatory, or statutory reason for the denial and information on how to appeal the denial. The Benefits Improvement and Protection Act (BIPA) of 2000 changed the appeals process and created a new independent review (the qualified independent contractors or QICs), which has not yet been implemented.

Explanation of Provision

The provision would require that notice of and decisions from determinations, redeterminations, reconsiderations, ALJ appeals, and DAB appeals be written in a manner understandable to a beneficiary and that includes, as appropriate, reasons for the determination or decision and notice of the right to appeal decisions and the process for further appeal. The initial determination of a claim would also be specifically required to include: the reasons for the determination, including whether a local review policy or coverage determination was used and the procedures for obtaining additional information (including, upon request, the specific provision of the policy manual, or regulation used in making the determination). Redeterminations, the first level of appeal, would also specifically be required to include: the specific reasons for the decision; as appropriate a summary of the clinical or scientific evidence used in making the redetermination; and a description of the procedures for obtaining additional information concerning the redetermination (including, upon request, the specific provision of the policy manual, or regulation used in making the determination).

Effective Date

Upon enactment.

Reason for Change

Currently, Medicare only provides beneficiaries with a brief statement about the initial determination of her claim on the Medicare Summary Notice. This provision provides additional information to beneficiaries (or providers who appeal on their behalf) about Medicare's denial of their claim for benefits; the reasons for the denial, and the rights to further appeal so that beneficiaries can have a clear and concise understanding of decisions affecting their medical care.

(D) Qualified Independent Contractors.

Current Law

BIPA established a new and independent second level of appeal called the qualified independent contractors. BIPA called for at least 12 QICs. The QICs have not yet been implemented.

Explanation of Provision

The provision would clarify eligibility requirements for qualified independent contractors and their reviewer employees including medical and legal expertise, independence requirements, and the prohibition on compensation being linked to decisions rendered. The required number of qualified independent contractors would be reduced from not fewer than twelve to not fewer than four.

Effective Date

The provisions regarding the eligibility requirements of QICs and QIC reviews would be effective as if included in the enactment of BIPA.

Reason for Change

The BIPA 2000 law laid out broad provisions for revision of the Medicare appeals process. These provisions strengthen the appeals process by enhancing the criteria related to the independence and expertise of the reviewers and review entities.

Section 934. Prepayment Review.

Current Law

No explicit statutory instruction. Under administrative authorities, CMS has instructed the contractors to use random prepayment reviews to develop contractor-wide and program-wide error rates. Non-random payment reviews are permitted in certain circumstances laid out in instructions to the contractors.

Explanation of Provision

Medicare contractors would be permitted to conduct random prepayment reviews only to develop a contractor-wide or program-wide error rate or such additional circumstances as the Secretary provides for in regulations that were developed in consultation with providers and suppliers. Random prepayment review would only be permitted in accordance with standard protocol developed by the Secretary. Nonrandom payment reviews would be permitted only when there was a likelihood of sustained or high level of payment error. The Secretary would be required to issue regulations regarding the termination and termination dates of non-random

prepayment review. Variation in termination dates would be permitted depending upon the differences in the circumstances triggering prepayment review.

Effective Date

The Secretary would be required to issue the required regulations not later than one year after enactment. The provision regarding the use of standard protocols when conducting prepayment reviews would apply to random prepayment reviews conducted on or after the date specified by the Secretary (but not later than one year after enactment). The remaining provisions would be effective one year after enactment.

Reason for Change

These provisions build greater consistency and predictability into Medicare's rules for prepayment review, while protecting program integrity.

Section 935. Recovery of Overpayments.

Current Law

No explicit statutory instruction. Under administrative authorities, CMS negotiates extended repayment plans with providers that need additional time to repay Medicare overpayments.

Explanation of Provision

In situations where repaying an Medicare overpayment within 30 days would be a hardship for a provider or supplier, the Secretary would be required to enter into an extended repayment plan of at least six months duration. The repayment plan would not be permitted to go beyond three years (or five years in the case of extreme hardship, as determined by the Secretary). Interest would be required to accrue on the balance through the repayment period. Hardship would be defined if, for providers that file cost reports, the aggregate amount of the overpayment exceeded 10 percent of the amount paid by Medicare to the provider for the time period covered by the most recently submitted cost report. In the case of a provider or supplier that is not required to file a cost report, hardship would be defined if the aggregate amount of the overpayment exceeded 10 percent of the amount paid under Medicare for the previous calendar year. The Secretary would be required to develop rules for the case of a provider or supplier that was not paid under Medicare during the previous year or for only a portion of the year. Any other repayment plans that a provider or supplier has with the Secretary, would not be taken into account by the Secretary in calculating hardship. If the Secretary has reason to suspect that the provider or supplier may file for bankruptcy or otherwise cease to do business or discontinue participation in Medicare or there is an indication of fraud or abuse, the Secretary would not be obligated to enter into an extended repayment plan with the provider or supplier. If a provider or supplier fails to make a payment according to the repayment plan, the Secretary would be permitted to immediately seek to offset or recover the total outstanding balance of the repayment plan, including interest.

The Secretary would be prohibited from recouping any overpayments until a reconsideration-level appeal (or a redetermination by the fiscal intermediary or carrier if the QICs are not yet in place) was decided, if a reconsideration was requested. Interest would be required to be paid to the provider if the appeal was successful (beginning from the time the overpayment is recouped) or that interest would be required to be paid to the Secretary if the appeal was unsuccessful (and if the overpayment was not paid to the Secretary).

Extrapolation would be limited to those circumstances where there is a sustained or high level of payment error, as defined by the Secretary in regulation, or document educational intervention has failed to correct the payment error.

Medicare contractors would be permitted to request the periodic production of records or supporting documentation for a limited sample of submitted claims to ensure that the previous practice is not continuing in the case of a provider or supplier with prior overpayments.

The Secretary would be able to use consent settlements to settle projected overpayments under certain conditions. Specifically the Secretary would be required to communicate with the provider or supplier that medical record review has indicated an overpayment exists, the nature of the problems identified, the steps needed to address the problems, and afford the provider or supplier 45 days to furnish additional information regarding the medical records for the claims reviewed. If, after reviewing the additional information an overpayment continues to exist, the Secretary would be required to provide notice and an explanation of the determination and then may offer the provider two mechanisms to resolve the overpayment: either an opportunity for a statistically valid random sample or a consent settlement (without waiving any appeal rights).

The Secretary would be required to establish a process to provide notice to certain providers and suppliers in cases where billing codes were over-utilized by members of that class in certain areas, in consultation with organizations that represent the affected provider or supplier class.

If post-payment audits were conducted, the Medicare contractor would be required to provide the provider or supplier with written notice of the intent to conduct the audit. The contractor would further be required to give the provider or supplier a full and understandable explanation of the findings of the audit and permit the development of an appropriate corrective action plan, inform the provider or supplier of appeal rights and consent settlement options, and give the provider or supplier the opportunity to provide additional information to the contractor, unless notice or findings would compromise any law enforcement activities.

The Secretary would be required to establish a standard methodology for Medicare contractors to use in selecting a sample of claims for review in cases of abnormal billing patterns.

Effective Date

In general, the provisions would be effective upon enactment. The limitation on extrapolation would apply to samples initiated after the date that is one year after the date of enactment. The Secretary would be required to establish the process for notice of over-utilization of billing codes not later than one year after enactment. The Secretary would be required to establish a standard methodology for selecting sample claims for abnormal billing patterns not later than one year after enactment.

Reason for Change

These provisions build greater consistency and predictability into Medicare's rules for recovery of overpayments, while protecting program integrity.

Section 936. Provider Enrollment Process; Right of Appeal.

Current Law

No explicit statutory instruction. Under administrative authorities, CMS has established provider enrollment processes in instructions to the contractors.

Explanation of Provision

The Secretary would be required to establish in regulation a provider enrollment process with hearing rights in the case of a denial or non-renewal. The process would be required to include deadlines for actions on applications for enrollment and enrollment renewals. The Secretary would be required to monitor the performance of the Medicare contractors in meeting the deadlines he establishes. Before changing provider enrollment forms, the Secretary would be required to consult with providers and suppliers. The provision would also establish hearing rights in cases where the applications have been denied.

Effective Date

The enrollment process would be required to be established within six months of enactment. The consultation process on provider enrollment forms would be required for changes in the form beginning January 1, 2004. The provision of hearing rights would apply to denials that occur one year after enactment or an earlier date specified by the Secretary.

Reason for Change

This provision gives providers and suppliers an opportunity to appeal denials of their applications to participate in the Medicare program.

Section 937. Process for Correction of Minor Errors and Omissions on Claims without Pursuing Appeals Process.

Current Law

No provision.

Explanation of Provision

This provision would require the Secretary to establish a process so providers and suppliers could correct minor errors in claims that were submitted for payment.

Effective Date

The proposal would require that the process be developed not later than one year after enactment.

Reason for Change

Many of the providers and suppliers who testified before the Subcommittee or contacted members directly emphasized the need to create a process in which they could correct claims that were denied because they were incomplete or contained minor errors without having to pursue a formal appeal. This provision instructs the Secretary to create such a process, which will alleviate pressure on the appeals system. The Committees would be concerned, however, if this process were to become an incentive for providers to knowingly or negligently submit incomplete information.

The Committees intend that the process for correction of minor errors and omissions on claims cover both the submission of prepayment and post-payment review claims. For example, if in the case of a home health claim, the physician has signed the plan of care and/or physician's order but has not dated it, the claim shall be returned to the home health agency and may be resubmitted by the home health agency with any incomplete or missing information without having to appeal the claim.

Section 938. Prior Determination Process for Certain Items and Services; Advance Beneficiary Notices.

Current Law

Medicare law prohibits payment for items and services that are not medically reasonable and necessary for the diagnosis or treatment of an illness or an injury. Under certain circumstances, however, Medicare will pay for non-covered services that have been provided if both the beneficiary and the provider of the services did not know and could not have reasonably been expected to know that Medicare payment would not be made for these services.

A provider may be held liable for providing uncovered services, if, for example, specific requirements are published by the Medicare contractor or the provider has received a denial or reduction of payment on the same or similar service. In cases where the provider believes that the service may not be covered as reasonable and necessary, an acceptable advance notice of Medicare's possible denial of payment must be given to the patient if the provider does not want to accept financial responsibility for the service. The notice must be given in writing, in advance of providing the service; include the patient's name, date and description of service as well as reasons why the service would not be covered; and must be signed and dated by the patient to indicate that the beneficiary will assume financial liability for the service if Medicare payment is denied or reduced.

Explanation of Provision

The Secretary would be required to establish a process through regulation where physicians and beneficiaries can establish whether Medicare covers certain categories of items and services before such services are provided. An eligible requestor would be a physician, but only in case of items and services for which the physician is paid directly and a Medicare beneficiary who receives an advance beneficiary notice from a physician would receive direct payment for that service. The provisions would establish that: (1) such prior determinations would be binding on the Medicare contractor, absent fraud or misrepresentation of facts, (2) the right to redetermination in the case of a denial, (3) the applicability of existing deadlines with respect to those redeterminations, (4) that contractors' advance determinations (and redeterminations) are not subject to further administrative or judicial review, and (5) an individual retains all rights to usual administrative or judicial review after receiving the service or receiving a determination that a service would not be covered. These provisions would not affect a Medicare beneficiary's right not to seek an advance determination. The prior determination process would be established in time to address such requests that are filed by 18 months of enactment. The Secretary would be required to collect data on the advance determinations and to establish a beneficiary outreach and education program. GAO is required to report on the use of the advance beneficiary notice and prior determination process within 18 months of its implementation.

Effective Date

Upon enactment.

Reason for Change

The Committees believe that when there is a question of whether Medicare will cover certain care for a beneficiary, the beneficiary should have the right to find out what would be covered before getting the service and risking financial liability. Doctors also should be able to make such a request on behalf of a particular patient. This provision is particularly important for seniors and disabled individuals who tend to be risk adverse and live on fixed incomes.

Subtitle V – Miscellaneous

Section 941. Policy Development Regarding Evaluation and Management (E&M) Documentation Guidelines.

Current Law

No provision.

Explanation of Provision

The Secretary would not be permitted to implement any new documentation guidelines for, or clinical examples of, evaluation and management (E&M) physician services unless the Secretary: (1) developed the guidelines in collaboration with practicing physicians (both generalists and specialists) and provided for an assessment of the proposed guidelines by the physician community, (2) established a plan containing specific goals, including a schedule, for improving the use of the guidelines, (3) conducted pilot projects to test modifications to the guidelines, (4) finds the guidelines have met established objectives, and (5) established and implemented an education program on the use of the guidelines with appropriate outreach. The Secretary would make changes to existing E&M guidelines to reduce paperwork burdens on physicians. The provision establishes objectives for modifications of the E&M guidelines: (1) identify clinically relevant documentation needed to code accurately and assess coding levels accurately, (2) decrease the non-clinically pertinent documentation in the medical record, (3) increase reviewers accuracy, and (4) educate physicians and reviewers.

The pilot projects would be required to be conducted on a voluntary basis in consultation with practicing physicians (both generalists and specialists) and be of sufficient length to educate physicians and contractors on E&M guidelines. A range of different projects would be established and include at least one project: using a physician peer review method, using an alternative method based on face-to-face encounter time with the patient, in a rural area, outside a rural area, and where physicians bill under physician services in a teaching setting and non-teaching setting. The projects would examine the effect of modified E&M guidelines on different types of physician practices in terms of the cost of compliance. Data collected under these projects would not be the basis for overpayment demands or post-payment audits. This protection would apply to claims filed as part of the project, would last the duration of the project, and would last for as long as the provider participated in the project. Each pilot conducted would examine the effect of the new E&M documentation guidelines on different types of physician practices (including those with fewer than 10 full-time equivalent employees) and the costs of physician compliance including education implementation, auditing, and monitoring. The Secretary would be required to submit periodic reports to Congress on these pilot projects.

The provision would require a study of an alternative system for documenting physician claims. Specifically the Secretary would be required to study developing a simpler system for documenting claims for evaluation and management services and to consider systems other than current coding and documentation requirements. The Secretary would be required to consult

with practicing physicians in designing and carrying out the study. This study would be due to Congress no later than October 1, 2005. MedPAC would be required to analyze the results of the study and report to Congress. The Secretary would also be required to study the appropriateness of coding in cases of extended office visits in which no diagnosis is made and report to Congress no later than October 1, 2005. The Secretary would be required to include in the report recommendations on how to code appropriately for these visits in a manner that takes into account the amount of time the physician spent with the patient.

Effective Date

Upon enactment.

Reason for Change

This provision is designed to promote greater consultation with practicing physicians with regard to the complicated evaluation and management and coding requirements governing Medicare payment for physician services.

Section 942. Improvement in Oversight of Technology and Coverage.

(a) Council for Technology and Innovation.

Current Law

No provision.

Explanation of Provision

The Secretary would be required to establish a Council for Technology and Innovation within CMS. The council would be composed of senior CMS staff and clinicians with a chairperson designated by the Secretary who reports to the CMS Administrator. The Chairperson would serve as the Executive Coordinator for Technology and Innovation would be the single point of contact for outside groups and entities regarding Medicare coverage, coding, and payment processes. The Council would coordinate Medicare's coverage, coding, and payment processes as well as information exchange with other entities with respect to new technologies and procedures, including drug therapies.

If the National Committee on Vital and Health Statistics has not made a recommendation to the Secretary by enactment regarding implementation of the ICD-10 coding system for diagnosis and procedures, the Secretary may adopt such standards one year after the date of enactment.

Effective Date

Upon enactment.

Reason for Change

After the FDA pre-market approval, the Medicare program does a second evaluation of breakthrough technologies to determine effectiveness and cost of those technologies compared to existing technologies. The review is necessary and appropriate, but it can take months between FDA approval and the availability of new technology for Medicare beneficiaries. By coordinating FDA and CMS approval of breakthrough medical devices, where feasible, this provision is intended to facilitate a more efficient process for the coverage of certain new technology by the Medicare program.

The ICD-9 coding system was adopted in 1979, and remains in effect for diagnosis and procedure coding in hospital inpatient and outpatient settings. ICD-9 has "run out" of codes for certain new procedures. For example, no code was available for the anthrax attack in 2001. NCVHS began investigating adoption of an updated coding system -- ICD-10 -- in 1990. ICD-10 is more clinically accurate, and has available codes for new technologies and procedures. In 1996, as part of the Health Insurance Portability and Accountability Act (HIPAA) of 1996, Congress required NCVHS to make a recommendation on adoption prior to Secretarial approval. To date, NCVHS still has not issued a recommendation.

ICD-9 has run out of codes for new technologies and procedures. ICD-10 has room for those procedures, which would improve accuracy in claims processing. Every developed country in the world except the US and Israel has adopted ICD-10 as the standard coding system because it is superior to ICD-9. Some hospitals are eager to adopt ICD-10 because ultimately they believe it would improve efficiency. The Committee agrees, although nothing in this provision requires the Secretary to adopt the ICD-10 in any health care setting.

(b) Methods for Determining Payment Basis for New Lab Tests.

Current Law

Outpatient clinical diagnostic laboratory tests are paid on the basis of area wide fee schedules. The law establishes cap on the payment amounts, which is currently set at 74 percent of the median for all fee schedules for that test. The cap is set at 100 percent of the median for tests performed after January 1,2001 that the Secretary determines are new tests for which no limitation amount has previously been established.

Explanation of Provision

The Secretary would be required to establish procedures (by regulation) for determining the basis for and amount of payments for new clinical diagnostic laboratory tests. New laboratory tests would be defined as those assigned a new, or substantially revised Health Care Procedure Coding System (HCPCS) code on or after January 1, 2005. The Secretary, as part of this procedure, would be required to: (1) provide a list (on an Internet site or other appropriate venue) of tests for which payments are being established in that year, (2) publish a notice of a meeting in the *Federal Register* on the day the list becomes available, (3) hold the public meeting no earlier than 30 days after the notice to receive public comments and

recommendations, (4) take into account the comments, recommendations and accompanying data in both proposed and final payment determinations. The Secretary would set forth the criteria for making these determinations; make public the available data considered in making such determinations; and could convene other public meetings as necessary.

Effective Date

Effective for codes assigned on or after January 1, 2005.

(c) GAO Study on Improvements in External Data Collection for Use in the Medicare Inpatient Payment System.

Current Law

No provision.

Explanation of Provision

GAO would be required to study which external data could be collected by CMS in a shorter time frame for use in calculating payments for inpatient hospital services. GAO could evaluate feasibility and appropriateness of using quarterly samples or special surveys and would include an analysis of whether other executive agencies would better suited to collect this information. The report would be due to Congress no later than October 1, 2004.

Effective Date

Upon enactment.

Section 943. Treatment of Hospitals for Certain Services Under Medicare Secondary Payer (MSP) Provisions.

Current Law

In certain instances when a beneficiary has other insurance coverage, Medicare becomes the secondary insurance. Medicare Secondary Payer is the Medicare program's coordination of benefits with other insurers. Section 1862(b)(6) of the Social Security Act requires an entity furnishing a Part B service to obtain information from the beneficiary on whether other insurance coverage is available.

Explanation of Provision

The Secretary would not require a hospital or a critical access hospital to ask questions or obtain information relating to the Medicare secondary payer provisions in the case of reference laboratory services if the same requirements are not imposed upon those provided by an independent laboratory. Reference laboratory services would be those clinical laboratory

diagnostic tests and interpretations of it that are furnished without a face-to-face encounter between the beneficiary and the hospital where the hospital submits a claim for the services.

Effective Date

Upon enactment.

Reason for Change

Hospitals would not have to directly contact each beneficiary on their retirement date, black lung status and other insurance information for reference laboratory services. While current law provisions for a claim containing valid insurance information are maintained, this provision is intended to reduce the amount of paperwork and regulatory burden related to the provision of these reference laboratory services by hospital-based entities.

Section 944. EMTALA Improvements.

Current Law

Medicare requires participating hospitals that operate an emergency room to provide necessary screening and stabilization services to a patient in order to determine whether an emergency medical situation exist prior to asking about insurance status of the patient.

Hospitals that are found to be in violation of Emergency Medical Treatment and Active Labor Act (EMTALA) requirements may face civil monetary penalties and termination of their provider agreement. Prior to imposing a civil monetary penalty, the Secretary is required to request a peer review organization (PRO), currently called quality improvement organizations (QIOs), to assess whether the involved beneficiary had an emergency condition, which had not been stabilized and provide a report on its findings. Except in the case where a delay would jeopardize the health or safety, the Secretary provides 60-day period for the requested PRO review.

EMTALA is enforced by general guidelines issued by CMS. Patients or present to the emergency room and request services (or another person does so on their behalf are required to be screened and stabilized.

Explanation of Provisions

Emergency room services provided to screen and stabilize a Medicare beneficiary furnished after January 1, 2004, would be evaluated as reasonable and necessary on the basis of the information available to the treating physician or practitioner at the time the services were ordered; this would include the patient's presenting symptoms or complaint and not the patient's principal diagnosis. The Secretary would not be able to consider the frequency with which the item or service was provided to the patient before or after the time of admission or visit.

The Secretary would be required to establish a procedure to notify hospitals and physicians when an EMTALA investigation is closed.

Except in the case where a delay would jeopardize the health and safety of individuals, the Secretary would be required to request a PRO review before making a compliance determination that would terminate a hospital's Medicare participation because of EMTALA violations and provide a period of 5 business days for such review. The PRO shall provide a copy of the report on its findings to the hospital or physician that is consistent with existing confidentiality requirements. This provision would apply to terminations initiated on or after enactment

The provision also clarifies the responsibility of the hospital when the individual does not request examination or treatment for an emergency condition.

Effective Date

Upon enactment.

Reason for Change

Providers have reported that some Medicare contractors are looking at final diagnoses (not presenting symptoms) in applying local medical review policies (LMRPs) that match particular tests to particular diagnoses-if a test does not match a listed diagnosis, payment is denied. Other claims are reportedly being denied based on LMRPs that set frequency limits for certain tests-if the test's use in the emergency room exceeds a frequency limit, payment is denied. In its January 2001 report entitled The Emergency Medical Treatment and Labor Act: The Enforcement Process, at the OIG recommended that CMS ensure that peer review occurs before a provider is terminated from the Medicare program for an EMTALA violation. This section implements that recommendation, making the current discretionary PRO review process mandatory in cases that involve a question of medical judgment. Finally, it clarifies CMS guidelines for persons or individuals who arrive at the emergency room for non-emergency services.

Section 945. Emergency Medical Treatment and Active Labor (EMTALA) Task Force.

Current Law

No provision.

Explanation of Provision

The Secretary would be required to establish a 17-member technical advisory group under specified requirements to review issues related to EMTALA. The advisory group would be comprised of: the CMS Administrator; the OIG; four hospital representatives who have EMTALA experience, (including 1 person from a public hospital and two of whom have not

experienced EMTALA violations); five practicing physicians with EMTALA experience; two patient representatives; two regional CMS staff involved in EMTALA investigations; one representative from a state survey organization and one from a PRO. The Secretary would select qualified individuals who are nominated by organizations representing providers and patients.

The advisory group would be required to: (1) elect a member to as chairperson, (2) schedule its first meeting at the direction of the Secretary and meet at least twice a year subsequently, (3) terminate 30 months after the date of its first meeting, and (4) be exempt from the Federal Advisory Committee Act. The advisory group would review EMTALA regulations; provide advice and recommendations to the Secretary; solicit public comments from interested parties; and disseminate information on the application of the EMTALA regulations.

Effective Date

Upon enactment.

Reason for Change

In its January 2001 report entitled The Emergency Medical Treatment and Labor Act: The Enforcement Process, the OIG recommended that CMS establish an EMTALA technical advisory group that includes all EMTALA stakeholders to help the agency resolve any emerging issues related to implementation of the law. Some of these current issues include specialists who refuse to service on call panels and inconsistencies between Stat and Federal law governing emergency medical services. In its June 2001 report entitled Emergency Care: EMTALA Implementations and Enforcement Issues, the GAO also concluded that the establishment of a technical advisory group could help CMS work with hospitals and physicians to achieve the goals of EMTALA and avoid creating unnecessary burdens for providers. This section implements the OIG recommendation, establishing a 19-member technical advisory group within HHS.

Section 946. Authorizing Use of Arrangements to Provide Core Hospice Services in Certain Circumstances.

Current Law

A hospice is a public agency or private organization, which is primarily engaged in providing and making available certain care to a terminally ill Medicare beneficiary under a written plan.

Explanation of Provisions

A hospice would be permitted to: (1) enter into arrangements with another hospice program to provide care in extraordinary, exigent or other non-routine circumstances, such as unanticipated high patient loads, staffing shortages due to illness, or temporary travel by a patient outside the hospice's service area, and (2) bill and be paid for the hospice care provided under these arrangements.

Effective Date

For hospice care provided on or after enactment.

Reason for Change

Hospice programs would be allowed to use personnel from other hospice programs to provide services to hospice patients. The program is given the flexibility so that a hospice program could continue to serve a patient if he or she was temporarily out of the area due to travel. Otherwise, the provision of the care to the patient might be delayed by the paperwork and requirements in starting up a new service at another agency. It is the intent of Congress that the originating hospice maintains control over the billing and quality of care.

Section 947. Application of OSHA Bloodborne Pathogens Standards to Certain Hospitals.

Current Law

Section 1866 establishes certain conditions of participation that providers must meet in order to participate in Medicare.

Explanation of Provision

Public hospitals that are not otherwise subject to the Occupational Safety and Health Act of 1970 would be required to comply with the Bloodborne Pathogens standard under section 1910.1030 of title 29 of the Code of Federal Regulations. A hospital that fails to comply with the requirement would be subject to a civil monetary penalty, but would not be terminated from participating in Medicare.

Effective Date

The provision would apply to hospitals as of July 1, 2004.

Reason for Change

Last year, Congress enacted legislation that requires hospitals to utilize safe needles. However, that legislation only applies to non-government hospitals. Twenty-four states have similar requirements on public hospitals. This provision would protect the health and safety of health care workers in those facilities by requiring public hospitals in the other 26 states and the District of Columbia to comply with this important standard.

Section 948. BIPA-Related Technical Amendments and Corrections.

Current Law

BIPA established an advisory process for national coverage determinations where panels of experts formed by advisory committees could forward their recommendations directly to the Secretary without prior approval of the advisory committee or the Executive Committee.

Explanation of Provision

The statutory reference in BIPA would be changed from the Social Security Act to the Public Health Service Act. Other BIPA references would be changed from a policy to a determinations.

Effective Date

The provision would be effective as if included in BIPA.

Section 949. Conforming Authority to Waive A Program Exclusion.

Current Law

The Secretary is required to exclude individuals and entities from participation in Federal Health Programs that are (1) convicted of a criminal offense related to health care delivery under Medicare or under State health programs, (2) convicted of a criminal offense related to patient abuse or neglect under Federal or State law, (3) convicted of a felony relating to fraud, theft, or financial misconduct relating to a health care program finance or operated by the Federal, State or local government, or (4) convicted of a felony related to a controlled substance.

Explanation of Provisions

The Administrator of a Federal health program would be permitted to waive certain 5-year exclusions if the exclusion of a sole community physician or source of specialized services in a community would impose a hardship. The mandatory exclusions that could be waived would be those related to convictions associated with program-related crimes, health care fraud and controlled substances.

Effective Date

Upon enactment.

Reason for Change

The Office of Inspector General requested this technical correction.

Section 950. Treatment of Certain Dental Claims.

Current Law

The Medicare benefit does not include most dental services. Some insurers may require a claim denial from Medicare before accepting the dental claim for payment review, even if Medicare does not cover the service.

Explanation of Provision

A group health plan providing supplemental or secondary coverage to Medicare beneficiaries would not be able to require dentists to obtain a claim denial from Medicare for non-covered dental services before paying the claim.

Effective Date

The provision would be effective 60 days after enactment.

Reason for Change

The Committees are concerned about private insurers requiring dentists to submit claims to Medicare for non-covered services before making a determination for coverage under the group health plan. Because of this requirement, dentists have been forced to enroll in the Medicare program to submit claims for services that are categorically excluded from Medicare coverage. Dentists view Medicare's enrollment application process as overly burdensome, particularly in light of the fact that Medicare does not cover most dental services. This provision would alleviate the enrollment burden placed on dentists providing services clearly excluded from Medicare coverage, consistent with the overarching goal of this legislation to reduce regulatory burdens.

Section 951. Furnishing Hospitals with Information to Compute DSH Formula.

Current Law

Disproportionate share hospital (DSH) payments under Medicare are calculated using a formula that includes the number of patient days for patients eligible for Medicaid.

Explanation of Provision

The provision would require the Secretary to arrange for the information such as number of paid or unpaid Medicaid days, and the number of dual eligibles that hospitals need to calculate the Medicare DSH payment formula.

Effective Date

Upon enactment.

Reason for change

Hospitals find it difficult to compute certain critical numbers for the purposes of Medicare DSH such as unpaid days used by Medicaid eligibles or Medicare dual eligibles. This helps ensure accuracy for hospitals and for the Trust Fund.

Section 952. Revisions to Reassignment Provisions.

Current Law

Under certain circumstances, a person or entity other than the individual providing the service may receive Medicare payments.

Explanation of Provision

Entities, as defined by the Secretary, could receive Medicare payments for services provided by a physician or other person if the service was provided under a contractual arrangement and if the arrangement included joint and several liability (liability for several parties) for overpayment and the entities meet program integrity specifications determined by the Secretary.

Effective Date

The provision would be effective for payments made on or after one year after the date of enactment.

Section 953. Other Provisions.

Current Law

No provisions.

Explanation of Provision

GAO Report on Physician Compensation. No later than six months from enactment, GAO would be required to report to Congress on the appropriateness of the updates in the conversion factor including the appropriateness of the sustainable growth rate (SGR) formula for 2002 and subsequently. The report would examine the stability and the predictability of the updates and rate as well as the alternatives for use of the SGR in the updates. No later than 12 months from enactment, GAO would be required to report to Congress on all aspects of physician compensation for Medicare services. The report would review the alternatives for the physician fee schedule.

Annual Publication of List of National Coverage Determinations. The Secretary would be required to publish an annual list of national coverage determinations made under Medicare in the previous year. Included would be information on how to get more information about the determinations. The list would be published in an appropriate annual publication that is publicly available.

GAO Report on Flexibility in Applying Home Health Conditions of Participation to Patients Who Are Not Medicare Beneficiaries. The GAO would be required to report to Congress on the implications if the Medicare conditions of participation for home health agencies were applied flexibly with respect to groups or types of patients who are not Medicare beneficiaries. The report would include an analysis of the potential impact of this flexibility on clinical operations and the recipients of such services and an analysis of methods for monitoring the quality of care provided to these recipients. The report would be due no later than six month after enactment.

OIG Report on Notices Relating to Use of Hospital Lifetime Reserve Days. The Inspector General of HHS would be required to report to Congress on the extent to which hospitals provide notice to Medicare beneficiaries, in accordance with applicable requirements, before they use the 60 lifetime reserve days under the hospital benefit. The report would also include the appropriateness and feasibility of hospitals providing a notice to beneficiaries before they exhaust the lifetime reserve days. The report would be due no later than one year after enactment.

Effective Date

Upon enactment.

Section 954. Temporary Suspension of OASIS Requirement for Collection of Data on Non-Medicare and Non-Medicaid Claims.

Current law

Under the Conditions of Participation, home health agencies are required to complete the OASIS form on all patients.

Explanation of Provision

The OASIS data collected on non-Medicare or non-Medicaid patients is not collected or used by the Federal government. This provision suspends collection until the Secretary has published final regulations regarding the collection and use of this data. Moreover it requires a study of how the data is used by the agencies as well as recommendations from quality assessment experts. Agencies may continue collecting the data during the suspension.

Effective Date

Upon enactment.

Reason for change

Data mandates on the collection of data on non-Medicare and non-Medicaid patients by the Federal government should be carefully reviewed for privacy issues by the agency.

III. VOTES OF THE COMMITTEE

In compliance with clause 3(b) of rule XIII of the Rules of the House of Representatives, the following statements are made concerning the votes of the Committee on Ways and Means in its consideration of the bill, H.R. 2473.

MOTION TO REPORT THE BILL

The bill, H.R. 2473, as amended, was ordered favorably reported by a roll call vote of 25 yeas to 15 nays (with a quorum being present). The vote was as follows:

Representatives	Yea	Nay	Present	Representative	Yea	Nay	Present
Mr. Thomas.....	√			Mr. Rangel.....		√	
Mr. Crane.....	√			Mr. Stark.....		√	
Mr. Shaw.....	√			Mr. Matsui.....		√	
Mrs. Johnson.....	√			Mr. Levin.....		√	
Mr. Houghton.....	√			Mr. Cardin.....		√	
Mr. Herger.....	√			Mr. McDermott.....		√	
Mr. McCrery.....	√			Mr. Kleczka.....		√	
Mr. Camp.....	√			Mr. Lewis (GA).....		√	
Mr. Ramstad.....	√			Mr. Neal.....		√	
Mr. Nussle.....	√			Mr. McNulty.....		√	
Mr. Johnson.....	√			Mr. Jefferson.....		√	
Ms. Dunn.....	√			Mr. Tanner.....		√	
Mr. Collins.....	√			Mr. Becerra.....		√	
Mr. Portman.....	√			Mr. Doggett.....		√	
Mr. English.....	√			Mr. Pomeroy.....	√		
Mr. Hayworth.....	√			Mr. Sandlin……..			
Mr. Weller.....	√			Ms. Tubbs Jones….		√	
Mr. Hulshof.....	√						
Mr. McInnis.....	√						
Mr. Lewis (KY).....	√						
Mr. Foley.....	√						
Mr. Brady.....	√						
Mr. Ryan.....	√						
Mr. Cantor……..	√						

VOTES ON AMENDMENTS

An amendment in the nature of a substitute by Chairman Thomas was agreed to by a roll call vote of 25 yeas to 15 nays. The vote was as follows:

Representatives	Yea	Nay	Present	Representative	Yea	Nay	Present
Mr. Thomas.....	√			Mr. Rangel.....		√	
Mr. Crane.....	√			Mr. Stark.....		√	
Mr. Shaw.....	√			Mr. Matsui.....		√	
Mrs. Johnson.....	√			Mr. Levin.....		√	
Mr. Houghton.....	√			Mr. Cardin.....		√	
Mr. Herger.....	√			Mr. McDermott…		√	
Mr. McCrery.....	√			Mr. Kleczka.....		√	
Mr. Camp.....	√			Mr. Lewis (GA) ……		√	
Mr. Ramstad.....	√			Mr. Neal.....		√	
Mr. Nussle.....	√			Mr. McNulty.....		√	
Mr. Johnson.....	√			Mr. Jefferson.....		√	
Ms. Dunn.....	√			Mr. Tanner.....		√	
Mr. Collins.....	√			Mr. Becerra.....		√	
Mr. Portman.....	√			Mr. Doggett.....		√	
Mr. English.....	√			Mr. Pomeroy.....	√		
Mr. Hayworth.....	√			Mr. Sandlin……..			
Mr. Weller.....	√			Ms. Tubbs Jones….		√	
Mr. Hulshof.....	√						
Mr. McInnis.....	√						
Mr. Lewis (KY).....	√						
Mr. Foley.....	√						
Mr. Brady.....	√						
Mr. Ryan.....	√						
Mr. Cantor……..	√						

A roll call vote was conducted on the following amendments to the Chairman's amendment in the nature of a substitute.

An amendment by Mr. Cardin, which would amend section 1860D-5(d) of the Social Security Act as proposed to be inserted by section 101, to require the U.S. Department of Health and Human Services to takes such steps as may be necessary to qualify and serve as a prescription drug plan sponsor and to offer a prescription drug plan that offers standard coverage throughout the United States, was defeated by a roll call vote of 15 yeas to 23 nays. The vote was as follows:

Representatives	Yea	Nay	Present	Representative	Yea	Nay	Present
Mr. Thomas.....		√		Mr. Rangel.....	√		
Mr. Crane.....		√		Mr. Stark.....	√		
Mr. Shaw.....				Mr. Matsui.....	√		
Mrs. Johnson.....		√		Mr. Levin.....	√		
Mr. Houghton.....		√		Mr. Cardin.....	√		
Mr. Herger.....		√		Mr. McDermott.....	√		
Mr. McCrery.....		√		Mr. Kleczka.....	√		
Mr. Camp.....		√		Mr. Lewis (GA).....	√		
Mr. Ramstad.....		√		Mr. Neal.....	√		
Mr. Nussle.....		√		Mr. McNulty.....	√		
Mr. Johnson.....		√		Mr. Jefferson.....			
Ms. Dunn.....		√		Mr. Tanner.....	√		
Mr. Collins.....		√		Mr. Becerra.....	√		
Mr. Portman.....		√		Mr. Doggett.....	√		
Mr. English.....		√		Mr. Pomeroy.....	√		
Mr. Hayworth.....		√		Mr. Sandlin……..			
Mr. Weller.....		√		Ms. Tubbs Jones….	√		
Mr. Hulshof.....		√					
Mr. McInnis.....		√					
Mr. Lewis (KY).....		√					
Mr. Foley.....		√					
Mr. Brady.....		√					
Mr. Ryan.....		√					
Mr. Cantor……..		√					

An amendment by Mr. McDermott, to strike Subtitle C of Title II, eliminating the privatization of plans, was defeated by a roll call vote of 14 yeas to 23 nays. The vote was as follows:

Representatives	Yea	Nay	Present	Representative	Yea	Nay	Present
Mr. Thomas.....		√		Mr. Rangel.....	√		
Mr. Crane.....		√		Mr. Stark.....	√		
Mr. Shaw.....				Mr. Matsui.....	√		
Mrs. Johnson.....		√		Mr. Levin.....	√		
Mr. Houghton.....		√		Mr. Cardin.....	√		
Mr. Herger.....		√		Mr. McDermott.....	√		
Mr. McCrery.....		√		Mr. Kleczka.....	√		
Mr. Camp.....		√		Mr. Lewis (GA).....	√		
Mr. Ramstad.....		√		Mr. Neal.....	√		
Mr. Nussle.....		√		Mr. McNulty.....	√		
Mr. Johnson.....		√		Mr. Jefferson.....			
Ms. Dunn.....		√		Mr. Tanner.....	√		
Mr. Collins.....		√		Mr. Becerra.....	√		
Mr. Portman.....		√		Mr. Doggett.....	√		
Mr. English.....		√		Mr. Pomeroy.....	√		
Mr. Hayworth.....		√		Mr. Sandlin……..			
Mr. Weller.....		√		Ms. Tubbs Jones….			
Mr. Hulshof.....		√					
Mr. McInnis.....		√					
Mr. Lewis (KY).....		√					
Mr. Foley.....		√					
Mr. Brady.....		√					
Mr. Ryan.....		√					
Mr. Cantor……..		√					

An amendment by Mrs. Johnson, which would amend section 1848(c)(2)(H) of the Social Security Act, as proposed to be added by section 303(a)(1)(B), to direct the Secretary of Health and Human Services to expedite the process for adjusting existing CPT codes for costs associated with the administration of covered drugs, was agreed to by a roll call vote of 32 yeas to 5 nays. The vote was as follows:

Representatives	Yea	Nay	Present	Representative	Yea	Nay	Present
Mr. Thomas.....	√			Mr. Rangel.....		√	
Mr. Crane.....	√			Mr. Stark.....		√	
Mr. Shaw.....				Mr. Matsui.....	√		
Mrs. Johnson.....	√			Mr. Levin.....	√		
Mr. Houghton.....	√			Mr. Cardin.....	√		
Mr. Herger.....	√			Mr. McDermott.....	√		
Mr. McCrery.....	√			Mr. Kleczka.....	√		
Mr. Camp.....	√			Mr. Lewis (GA).....		√	
Mr. Ramstad.....	√			Mr. Neal.....		√	
Mr. Nussle.....	√			Mr. McNulty.....		√	
Mr. Johnson.....	√			Mr. Jefferson.....			
Ms. Dunn.....	√			Mr. Tanner.....	√		
Mr. Collins.....	√			Mr. Becerra.....	√		
Mr. Portman.....	√			Mr. Doggett.....	√		
Mr. English.....	√			Mr. Pomeroy.....	√		
Mr. Hayworth.....	√			Mr. Sandlin……..			
Mr. Weller.....	√			Ms. Tubbs Jones….			
Mr. Hulshof.....	√						
Mr. McInnis.....	√						
Mr. Lewis (KY).....	√						
Mr. Foley.....	√						
Mr. Brady.....	√						
Mr. Ryan.....	√						
Mr. Cantor……..	√						

An amendment by Mr. Doggett, which would amend section 1860D-3(c) of the Social Security Act as proposed to be inserted by section 101, to require each participating manufacturer of a covered outpatient drug to enter into arrangements with prescription drug plan sponsors or entities offering an MA-EFF prescription plan, was defeated by a roll call vote of 12 yeas to 23 nays. The vote was as follows:

Representatives	Yea	Nay	Present	Representative	Yea	Nay	Present
Mr. Thomas.....		√		Mr. Rangel.....	√		
Mr. Crane.....		√		Mr. Stark.....	√		
Mr. Shaw.....				Mr. Matsui.....	√		
Mrs. Johnson.....		√		Mr. Levin.....	√		
Mr. Houghton.....		√		Mr. Cardin.....	√		
Mr. Herger.....		√		Mr. McDermott.....	√		
Mr. McCrery.....		√		Mr. Kleczka.....	√		
Mr. Camp.....		√		Mr. Lewis (GA).....	√		
Mr. Ramstad.....		√		Mr. Neal.....	√		
Mr. Nussle.....		√		Mr. McNulty.....	√		
Mr. Johnson.....		√		Mr. Jefferson.....			
Ms. Dunn.....		√		Mr. Tanner.....			
Mr. Collins.....		√		Mr. Becerra.....	√		
Mr. Portman.....		√		Mr. Doggett.....	√		
Mr. English.....		√		Mr. Pomeroy.....		√	
Mr. Hayworth.....		√		Mr. Sandlin……..			
Mr. Weller.....				Ms. Tubbs Jones….			
Mr. Hulshof.....		√					
Mr. McInnis.....		√					
Mr. Lewis (KY).....		√					
Mr. Foley.....		√					
Mr. Brady.....		√					
Mr. Ryan.....		√					
Mr. Cantor……..		√					

An en bloc amendment by Mr. Collins, which would add at the end of section 1851(j) of the Social Security Act, as added by section 102(a), to apply fee-for-service Medicare+Choice rules to prescription drug benefits; and as added by section 221(d), to provide the same treatment for premiums for MA private fee-for-service plans, was agreed to by a roll call vote of 24 yeas to 12 nays, with 2 voting present. The vote was as follows:

Representatives	Yea	Nay	Present	Representative	Yea	Nay	Present
Mr. Thomas.....	√			Mr. Rangel.....		√	
Mr. Crane.....	√			Mr. Stark.....		√	
Mr. Shaw.....	√			Mr. Matsui.....		√	
Mrs. Johnson.....	√			Mr. Levin.....		√	
Mr. Houghton.....	√			Mr. Cardin.....		√	
Mr. Herger.....	√			Mr. McDermott.....		√	
Mr. McCrery.....	√			Mr. Kleczka.....			√
Mr. Camp.....	√			Mr. Lewis (GA).....		√	
Mr. Ramstad.....	√			Mr. Neal.....		√	
Mr. Nussle.....	√			Mr. McNulty.....		√	
Mr. Johnson.....	√			Mr. Jefferson.....			
Ms. Dunn.....	√			Mr. Tanner.....			
Mr. Collins.....	√			Mr. Becerra.....			√
Mr. Portman.....	√			Mr. Doggett.....		√	
Mr. English.....	√			Mr. Pomeroy.....		√	
Mr. Hayworth.....	√			Mr. Sandlin……..			
Mr. Weller.....	√			Ms. Tubbs Jones….		√	
Mr. Hulshof.....	√						
Mr. McInnis.....	√						
Mr. Lewis (KY).....	√						
Mr. Foley.....	√						
Mr. Brady.....	√						
Mr. Ryan.....	√						
Mr. Cantor……..	√						

An amendment by Messrs. Nussle and Pomeroy, which would add the following new sections at the end of Title IV: Sec. 416 -- Adjustment to the Medicare Inpatient Hospital PPS Wage Index to Revise the Labor-Related Share of Such Index; and Sec. 417 -- Medicare Incentive Payment Program Improvements for Physician Scarcity, was agreed to by a roll call vote of 39 yeas to 0 nays, with 1 voting present. The vote was as follows:

Representatives	Yea	Nay	Present	Representative	Yea	Nay	Present
Mr. Thomas.....	√			Mr. Rangel.....	√		
Mr. Crane.....	√			Mr. Stark.....			√
Mr. Shaw.....	√			Mr. Matsui.....	√		
Mrs. Johnson.....	√			Mr. Levin.....	√		
Mr. Houghton.....	√			Mr. Cardin.....	√		
Mr. Herger.....	√			Mr. McDermott.....	√		
Mr. McCrery.....	√			Mr. Kleczka.....	√		
Mr. Camp.....	√			Mr. Lewis (GA).....	√		
Mr. Ramstad.....	√			Mr. Neal.....	√		
Mr. Nussle.....	√			Mr. McNulty.....	√		
Mr. Johnson.....	√			Mr. Jefferson.....	√		
Ms. Dunn.....	√			Mr. Tanner.....	√		
Mr. Collins.....	√			Mr. Becerra.....	√		
Mr. Portman.....	√			Mr. Doggett.....	√		
Mr. English.....	√			Mr. Pomeroy.....	√		
Mr. Hayworth.....	√			Mr. Sandlin……..			
Mr. Weller.....	√			Ms. Tubbs Jones….	√		
Mr. Hulshof.....	√						
Mr. McInnis.....	√						
Mr. Lewis (KY).....	√						
Mr. Foley.....	√						
Mr. Brady.....	√						
Mr. Ryan.....	√						
Mr. Cantor……..	√						

A substitute amendment by Mr. Stark was defeated by a roll call vote of 14 yeas to 26 nays. The vote was as follows:

Representatives	Yea	Nay	Present	Representative	Yea	Nay	Present
Mr. Thomas.....		√		Mr. Rangel.....	√		
Mr. Crane.....		√		Mr. Stark.....	√		
Mr. Shaw.....		√		Mr. Matsui.....	√		
Mrs. Johnson.....		√		Mr. Levin.....	√		
Mr. Houghton.....		√		Mr. Cardin.....	√		
Mr. Herger.....		√		Mr. McDermott.....	√		
Mr. McCrery.....		√		Mr. Kleczka.....	√		
Mr. Camp.....		√		Mr. Lewis (GA).....	√		
Mr. Ramstad.....		√		Mr. Neal.....	√		
Mr. Nussle.....		√		Mr. McNulty.....	√		
Mr. Johnson.....		√		Mr. Jefferson.....	√		
Ms. Dunn.....		√		Mr. Tanner.....		√	
Mr. Collins.....		√		Mr. Becerra.....	√		
Mr. Portman.....		√		Mr. Doggett.....	√		
Mr. English.....		√		Mr. Pomeroy.....		√	
Mr. Hayworth.....		√		Mr. Sandlin……..			
Mr. Weller.....		√		Ms. Tubbs Jones….	√		
Mr. Hulshof.....		√					
Mr. McInnis.....		√					
Mr. Lewis (KY).....		√					
Mr. Foley.....		√					
Mr. Brady.....		√					
Mr. Ryan.....		√					
Mr. Cantor……..		√					

IV. BUDGET EFFECTS OF THE BILL

The Congressional Budget Office has not submitted a final score of the legislation at the time of the filing of this report (July 15, 2003).

V. OTHER MATTERS REQUIRED TO BE DISCUSSED UNDER HOUSE RULES

A. Committee Oversight Findings and Recommendations

In compliance with clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the Committee reports that the need for this legislation was confirmed by the oversight hearings of the Subcommittee on Health. The hearings were as follows:

The Subcommittee on Health held a series of hearings on Medicare Reform during the 108th Congress to examine the implications of different proposals aimed at helping seniors gain more affordable access to prescription drugs. A list of these hearings may be found in this report in Section I. Introduction, Part C. Legislative History (Page xx).

B. Summary of General Performance Goals and Objectives

In compliance with clause 3(c)(4) of rule XIII of the Rules of the House of Representatives, the Committee states that the primary purpose of H.R. 2473 is to create a prescription drug benefit into the Medicare program while modernizing other aspects of the program.

C. Constitutional Authority Statement

In compliance with clause 3(d)(1) of rule XIII of the Rules of the House of Representatives, relating to constitutional Authority, the Committee states that the Committee's action in reporting the bill is derived from Article I of the Constitution, Section 8 ("The Congress shall have power to lay and collect taxes, duties, imposts, and excises, to pay the debts and to provide for * * * the General Welfare of the United States * * *").

VI. CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

Legislative Counsel has not prepared a Ramseyer at the time of the filing of this report (July 15, 2003).

VII. VIEWS